香港感染及傳染病醫學會
The Hong Kong Society for Infectious Diseases
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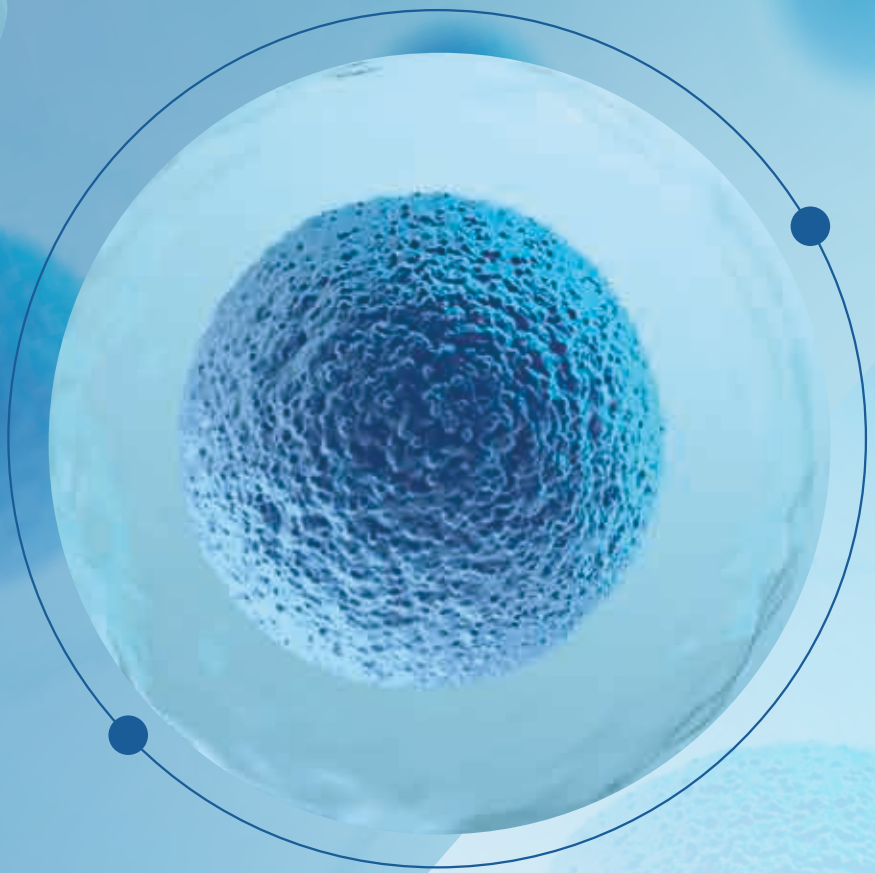
Infections in Oncology Patients

25th Annual Scientific Meeting

16 July 2022 (Saturday)

Co-organizer:

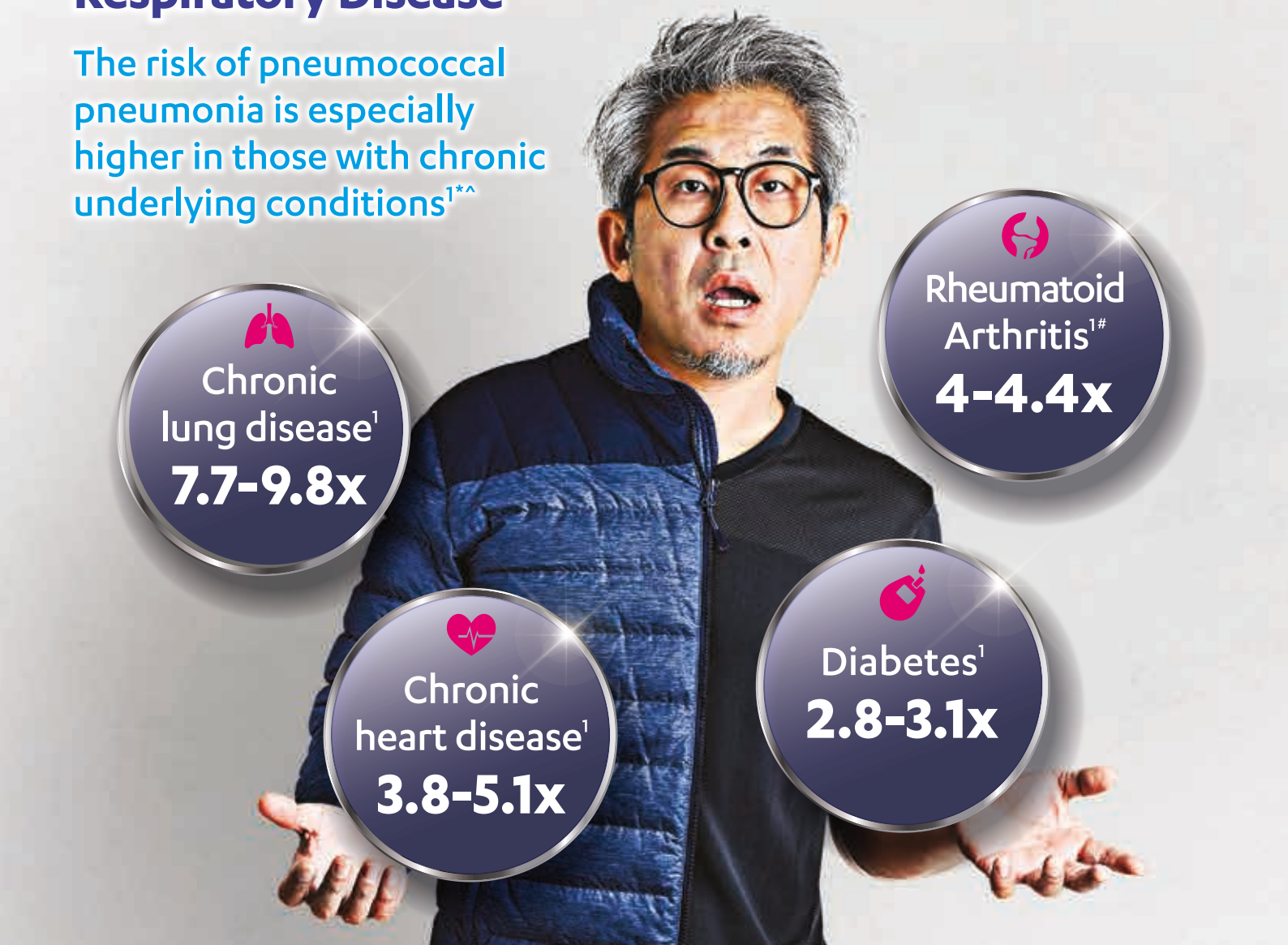
HONG KONG SOCIETY OF MEDICAL ONCOLOGY
香港內科腫瘤學會



Prevenar 13®
Pneumococcal polysaccharide conjugate vaccine (13-valent, adsorbed)

Don't Leave Vulnerable Adults Open To Other Vaccine-preventable Respiratory Disease

The risk of pneumococcal pneumonia is especially higher in those with chronic underlying conditions[1*^]



Several International Health Institutions Have Issued Specific Recommendations for Pneumococcal Vaccine Under the COVID-19 Pandemic[2-5]

- American College of Cardiology
- Centers for Disease Control & Prevention
- World Health Organization

* 18 years old or above; ^ Relative to their healthy counterparts; # Including Crohn's and Lupus; COVID-19 – Coronavirus Disease 2019

References: 1. Shea KM, Edelsburg J, Weycker D, et al. Rates of Pneumococcal Disease in Adults with Chronic Medical Conditions. Open forum infect Dis. 2014 May1(1): 1-9. 2. World Health Organization. Coronavirus disease (COVID-19) advice for the public: Myth Busters. Available at https://www.Who.int/emergencies/diseases/novel-coronavirus-2019/advice-for-public/myth-busters. Accessed 15 July 2021. 3. Brendan Mullen, ACC CLINICAL BULLETIN COVID-19 Clinical Guidance For the CV Care Team, American College of Cardiology, review and updated on March 6, 2020. Accessed 15 July 2021. 4. Immunization Action Coalition. Ask the Experts. COVID-19 and Routine Vaccination. Available at https://www.immunize.org/askexperts/experts_covid19.asp. Accessed 15 July 2021. 5. Centers for Disease Control and Prevention. Pneumococcal Vaccination. Available at: https://www.cdc.gov/pneumococcal/vaccination.html. Accessed 15 July 2021.

Summary of Product Information **GENERIC NAME:** Pneumococcal polysaccharide conjugate vaccine, 13-valent adsorbed **PRESENTATION:** homogeneous white suspension for intramuscular injection (0.5 mL), supplied as a pre-filled syringe. **INDICATION(s):** Active immunisation for the prevention of pneumococcal disease caused by *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F in adults and children aged more than 6 weeks of age. The immunisation schedules for Prevenar 13 should be based on official recommendations. **DOSAGE AND ADMINISTRATION:** The dose of Prevenar 13 is 0.5 mL given intramuscularly only. The immunisation schedules for Prevenar 13 should be based on official recommendations. Infants aged 6 weeks - 6 months: The primary infant series consists of three doses, with the first dose usually given at 2 months of age and with an interval of at least 1 month between doses. The first dose may be given as early as six weeks of age. A fourth (booster) dose is recommended after 12 months of age, and at least 2 months after the third dose. Preterm infants (<37 weeks gestation): the primary infant series consists of three doses, each of 0.5 mL, with the first dose given at 2 months of age and with an interval of at least 1 month between doses. The first may be given as early as six weeks of age. A fourth (booster) dose is recommended between 11 and 15 months of age. Unvaccinated children aged 7-11 months: 3 doses. Unvaccinated children aged 12-23 months: 2 doses. Unvaccinated children aged 24 months to 17 years: One single dose. Adults: One single dose. For more dosage information including special population who are at high risk of pneumococcal infection (such as sickle cell disease or HIV infection) or individuals with a haematopoietic stem cell transplant (HSCT), please refer to the full package insert. **PREGNANCY AND LACTATION:** Prevenar 13 is not indicated or recommended for use in pregnant women and has not been evaluated for potential harmful effects during pregnancy in humans. Safety during lactation has not been established. **CONTRAINDICATIONS:** Hypersensitivity to the active substances or to any of the excipients, or to diphtheria toxoid. Allergic reaction or anaphylactic reaction following prior administration of Prevenar (7-valent). **WARNING AND PRECAUTIONS:** Not for intravenous or intravascular administration. The administration should be postponed in subjects suffering from acute moderate or severe febrile illness. This vaccine will not protect against *Streptococcus pneumoniae* serotypes other than those included in the vaccine nor other microorganisms that cause invasive disease, pneumonia, or otitis media; may not protect all individuals receiving the vaccine from pneumococcal disease. Should not be given to individuals with thrombocytopenia or any coagulation disorder that would contraindicate intramuscular injection unless the potential benefit clearly outweighs the risk of administration. Individuals with impaired immune responsiveness may have reduced antibody response to active immunisation. Safety and immunogenicity data for Prevenar 13 are available for certain high-risk groups such as children and adolescents with sickle cell disease and children and adults with HIV infection or with a haematopoietic stem cell transplant. Data are not currently available for individuals in other immunocompromised groups (e.g., malignancy, or nephrotic syndrome) and vaccination should be considered on an individual basis. Children below 2 years old should receive the appropriate-for-age Prevenar 13 vaccination series. The potential risk of apnoea and the need for respiratory monitoring for 48-72h should be considered when administering the primary immunisation series to very premature infants (born ≤ 30 weeks of gestation), and particularly for those with a previous history of respiratory immaturity. Antipyretic treatment should be initiated according to local treatment guidelines. Prophylactic antipyretic medication is recommended for all children receiving Prevenar 13 simultaneously with vaccines containing whole cell pertussis and for children with seizure disorders or with a prior history of febrile seizures. **DRUG INTERACTIONS:** Different injectable vaccines should always be given at different injection sites. Infants and children aged 6 weeks to 5 years: Can be given with any of the following vaccine antigens, either as monovalent or combination vaccines: diphtheria, tetanus, acellular or whole cell pertussis, Haemophilus influenzae type b, inactivated poliomyelitis, hepatitis B, meningococcal serogroup C, measles, mumps, rubella and varicella. Can also be given concomitantly between 12-23 months with the tetanus toxoid conjugated meningococcal polysaccharide serogroup A, C, W and Y vaccine. Children aged 6 to 17 years of age and adults aged 18 to 49 years of age: No data are currently available regarding concomitant use with other vaccines. Adults aged 50 years and older Prevenar 13 may be administered concomitantly with the seasonal trivalent or quadrivalent inactivated influenza vaccine (TIV or QIV) with no interference with the immune responses to TIV or QIV. Concomitant use with other vaccines has not been investigated. **OVERDOSE:** Overdose with Prevenar 13 is unlikely due to its presentation as a pre-filled syringe **ADVERSE REACTION:** Children: Very Common – fever, any vaccination-site erythema, induration/swelling or pain/tenderness, vaccination-site erythema or induration/swelling 2.5 cm –7.0 cm (after toddler dose and in older children [age 2 to 5 years]), decreased appetite, drowsiness/increased sleep, restless sleep/decreased sleep, irritability; Common - fever greater than 39ºC; vaccination-site erythema or induration/swelling 2.5 cm - 7.0 cm (after infant series); vaccination-site pain/tenderness interfering with movement, diarrhoea, vomiting; rash; Children and adolescents aged 5 to 17 years of age: Very common - any vaccination-site erythema, induration/swelling or pain/tenderness, vaccination-site tenderness (including impaired movement), decreased appetite, drowsiness/increased sleep, restless sleep/decreased sleep, irritability; Common – fever, vomiting, diarrhea, headache, rash, urticaria or urticaria-like rash; Adults ≥18 years and the elderly: Very common - diarrhoea, vomiting (in adults aged 18 to 49 years), chills, fatigue, vaccination-site erythema, vaccination site induration/swelling, vaccination-site pain/tenderness, limitation of arm movement, generalised new joint pain/aggravated joint pain, generalised new muscle pain/aggravated muscle pain, decreased appetite, headache, rash; Common - vomiting (in adults aged 50 years and over), fever. Please refer to the full Prescribing Information for details **Reference:** HK LPD version Jan 2021 **Date of preparation:** MAR 2021 **Identifier number:** PR13-0321_Hong Kong **FULL PRESCRIBING INFORMATION IS AVAILABLE UPON REQUEST.**

Pfizer Corporation Hong Kong Limited
21/F., Kerry Centre, 683 King's Road, Quarry Bay, Hong Kong
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Website: www.pfizer.com.hk

PP-PNA-HKG-0110 August 2021

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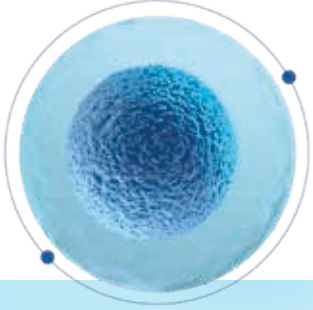

WELCOME MESSAGE

Dear distinguished guests, members and colleagues,

On behalf of The Hong Kong Society for Infectious Diseases, I welcome you all to our twenty-fifth Annual Scientific Meeting (ASM).

For the past two decades, our annual meetings have been the prime event for the healthcare professionals in Hong Kong to keep abreast of the latest update and cutting edge-advancement in scientific and clinical practice as well as the public health impact in infectious diseases. We staged last year's meeting to an on-line virtual platform to cope with the COVID-19 "new normal". This year, we are happy to continue to provide our virtual meeting as a platform to exchange ideas and experience with experts in the management of infection.

The main theme of ASM this year is on infections in oncology patients. We are honoured to have Dr. Wong Sin Yew from Singapore to share with us latest updates on COVID-19 prevention in oncology patients beyond vaccinations. As for the local experiences, we are privileged to have Dr. Eugenie Hui to give us an overview on treatment for HIV-related malignancies, Dr. Jonpaul Zee to share his experience in the diagnostics of infections in oncology patients, and Dr. Wilson Lam to bring us discussions on prevention of infections in oncology patients by vaccinations. Apart from lectures, this year we are resuming the clinical case presentation with on-line polling so that we can interact with you on the cases.

I would like to take this precious opportunity to express my heartfelt appreciation to our co-organizer Hong Kong Society of Medical Oncology, our invited oversea as well as local speakers, and all chairpersons for their invaluable contributions to the programme. The Society would also like to thank the industry for their unfailing support for making this event possible. Last but not least, my sincere thanks to the hard work of the organizing committee and meeting secretariat and your participation.

I wish all of you having a fruitful and enjoyable meeting today.

Dr. Ada Lin
President
The Hong Kong Society for Infectious Diseases

COUNCIL

The Hong Kong Society for Infectious Diseases
(April 2022 – March 2024)

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Dr. Bonnie Chun-kwan Wong

PROGRAMME

Time	Programme
13:45 - 13:50	**Welcome Speech** *Dr. Ada Lin, President, The Hong Kong Society for Infectious Diseases*
13:50 - 15:00	**Symposium I** *Chairpersons: Dr. Ada Lin and Dr. Lam Yim Kwan* **COVID-19 Prevention in Oncology Patients: What Else Beyond Vaccination?** *Dr. Wong Sin Yew* *Infectious Disease Specialist* *Infectious Disease Partners Pte Ltd, Gleneagles Medical* *Singapore* **Q & A** **Overview on Treatment for HIV-Related Malignancies** *Dr. Eugenie Hui* *Consultant* *Department of Medicine* *Queen Elizabeth Hospital, Hong Kong* **Q & A**
15:00 - 15:15	**Break**
15:15 - 16:05	**Symposium II** *Chairpersons: Dr. Jacky Chan and Dr. Bryan Li* **Diagnostics of Infections in Oncology Patients** *Dr. Jonpaul Zee* *Honorary Consultant in Infectious Disease* *Department of Pathology* *Hong Kong Sanatorium and Hospital, Hong Kong* **Prevention of Infections in Oncology Patients by Vaccinations** *Dr. Wilson Lam* *Specialist in Infectious Disease* *Private Practice* *Hong Kong* **Q & A**
16:05 - 16:45	**Clinical Case Presentation** *Chairperson: Dr. Winnie Sin* *Presenters: Dr. Chris Choi and Dr. Fion Luk* *Panelists: Dr. Helen Chan and Dr. Eugenie Hui*
16:45 - 16:50	**Closing Speech** *Dr. Wilson Lam, Vice-president, The Hong Kong Society for Infectious Diseases*

ACADEMIC ACCREDITATIONS

Organization	Points Accredited
Hong Kong College of Community Medicine	2
Hong Kong College of Emergency Medicine (Cat B)	2.5
The Hong Kong College of Family Physicians (Cat 5.2)	2
The Hong Kong College of Obstetricians and Gynaecologists	2.5
The Hong Kong College of Otorhinolaryngologists (Cat 2.2)	3
Hong Kong College of Paediatricans (Cat A)	3
The Hong Kong College of Pathologists (passive)	3
Hong Kong College of Physicians (passive)	2.5
Hong Kong College of Radiologists (Cat B)	2.5
The College of Surgeons of Hong Kong	3.5
MCHK Programme	3

FACULTY

The Council of the Society would like to thank the faculty members for their invaluable contributions to the 25th Annual Scientific Meeting

Dr. Helen Chan
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Consultant, Department of Medicine and Geriatrics, Princess Margaret Hospital, Hong Kong

Dr. Chris Choi
Resident, Department of Medicine & Geriatrics, Princess Margaret Hospital, Hong Kong

Dr. Eugenie Hui
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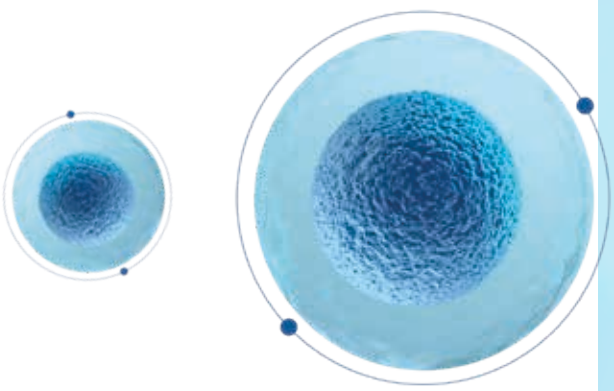
Dr. Wong Sin Yew
Infectious Disease Specialist, Infectious Disease Partners Pte Ltd, Gleneagles Medical, Singapore

Dr. Jonpaul Zee
Honorary Consultant in Infectious Disease, Department of Pathology, Hong Kong Sanatorium and Hospital, Hong Kong

COVID-19 Prevention in Oncology Patients: What Else Beyond Vaccination?

Dr. Wong Sin Yew
Infectious Disease Specialist, Infectious Disease Partners Pte Ltd, Gleneagles Medical, Singapore

While Coronavirus Disease 2019 (COVID-19) continues to threaten international health, vaccination against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has demonstrated to reduce the burden of disease. Nevertheless, vulnerable populations including immunocompromised persons (in particular patients with haematological malignancies and oncology patients on active chemotherapy) remain at risk for severe COVID-19. Monoclonal antibodies, offering rapid protection against COVID-19 irrespective of immune system status, are potential options for COVID-19 immuno-prophylaxis. Some combinations of monoclonal antibodies and antiviral therapies are already in use through emergency or temporary authorization for pre-exposure prophylaxis against COVID-19 or treatment of mild to moderate disease. These additional COVID-19 therapeutic options could provide potential solutions to mitigate the risk for severe outcome in the vulnerable population.



Overview on Treatment for HIV-Related Malignancies

Dr. Eugenie Hui

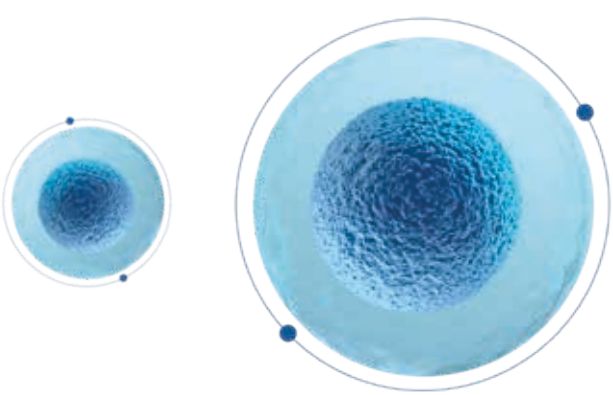
Consultant, Department of Medicine, Queen Elizabeth Hospital, Hong Kong

People with HIV (PWH) and AIDS have a higher incidence of malignancies as compared with the general population. HIV attacks and compromises the host immune system, making them susceptible to certain types of infections and cancers. AIDS-defining cancers, namely aggressive non-Hodgkin lymphoma, Kaposi sarcoma and invasive cervical cancer, are significantly more common in PWH due to their heavily suppressed immune system, commonly at diagnosis of HIV before treatment.

In the past two to three decades, with the advancement and wider availability of combination anti-retroviral therapy (cART) and appropriate supportive measures, many PWH are now ageing with the infection. Longer life expectancy leads to increased exposure to carcinogens and cancer-related viruses, making them also more vulnerable to develop other cancers that are not well-known to be strongly associated with AIDS.

Cancer treatment in PWH can be challenging. Their cancer journeys require expert and multidisciplinary specialist input in managing complex drug-drug interactions, multiple co-morbidities, co-infections/opportunistic infections and complicated social dilemmas. With prompt initiation of cART and appropriate prophylactic therapies, most cancers in PWH can be managed similarly to that as in the general population with comparable survival rates.

The world of evolving cancer therapies offers a better chance of survival for cancer patients. New technologies like immunotherapy and cell-based therapy involving manipulation of the hosts' immune system may seem controversial in this special population with already compromised immunity. However, recent experience shows that some of these therapies are not only feasible, but also safe and promising in optimizing cancer control and improving survival in this subgroup of cancer patients.



Diagnostics of Infections in Oncology Patients

Dr. Jonpaul Zee

Honorary Consultant in Infectious Disease, Department of Pathology, Hong Kong Sanatorium and Hospital, Hong Kong

Rapid and accurate identification of the invading pathogen and antimicrobial susceptibility are of utmost importance in improving outcome of oncology patient with infection. Blood culture is still the gold standard for diagnosis of blood stream infection (BSI), although its sensitivity is affected by many factors, such as fastidiousness of the pathogen and prior antibiotic exposure. In recent years, Matrix-Assisted Laser Desorption Ionization Time-Of-Flight Mass Spectrometry (MALDI-TOF MS) has provided a rapid solution for pathogen identification, omitting the time-consuming subculture routines and phenotypic testing. To supplement MALDI-TOF MS, commercial multiplex PCR platforms are now available to screen multiple targets simultaneously, including gram-negative/ positive bacteria, fungi and antimicrobial resistance genes with rapid turnaround-time. “Pre-culture” direct molecular detection is not widely used due to their lower sensitivity and specificity.

Commercial multiplex PCR platforms are also available for syndromic testing of varies body fluid, including respiratory tract specimen, stool, cerebral spinal fluid and joint fluid. However, the presence of pathogen nucleic acid does not equal to active infection, clinical judgement is needed when interpreting these results.

In the absence of a positive culture, invasive fungal disease (IFD) can be difficult to diagnosed in oncology patients. EORTC/MSGERC consensus definitions of IFD is now revised as more data on clinical features, performance of fungal markers (Galactomannan and BDG) and fungal PCR (Aspergillus and Pneumocystis jirovecii) are available.

Finally, broad-range PCR combined with metagenomics is a useful tool for culture negative specimen due to unusual organism or prior antibiotic exposure. However, their sensitivity and specificity are limited by the presence of human/ environmental DNA and other PCR inhibitors.

SYMPOSIUM II

Prevention of Infections in Oncology Patients by Vaccinations

Dr. Wilson Lam

Specialist in Infectious Disease, Private Practice, Hong Kong

Prevention is better than cure. And curing cancers is already a daunting task let alone doing that with background noises of nasty infections. Oncology patients are immuno-compromised to different degrees because of their underlying malignancies and treatment and hence are highly susceptible to various infectious diseases. Some of those infections are readily vaccine-PREVENTABLE but somehow vaccination is an often neglected area of clinical management. Prevention of common infectious diseases like influenza, pneumococcal infection, herpes zoster lead to better outcomes in terms of morbidities and mortalities. Furthermore, disruption of cancer treatment by even not severe infections is always a nuisance to both oncologists and patients and bring along unnecessary anxiety and inconveniences.

However, recommending immunizations for oncology patients are difficult as cancer treatment has changed substantially over the years and we often need to extrapolate already limited data from clinical studies to ensure we do the best to protect our patients, who are not well known to elicit strong immunological responses to vaccines in general. Also, there is a limited window period of time (i.e. before commencement of cancer treatment) which we can apply knowledge of immunisation in order to bring out the best of vaccines used in oncology patients.

In this talk, we shall discuss the general considerations of vaccination in oncology patients. We would all discuss about recommendations of different vaccines and their use with regard to oncology patients in Hong Kong. And it is inevitable that use of COVID-19 vaccines in immuno-compromised patients would be touched upon briefly as well.

ACKNOWLEDGEMENTS

The Council of the Society would like to extend their heartfelt thanks to the sponsors for their generous support to the 25th Annual Scientific Meeting

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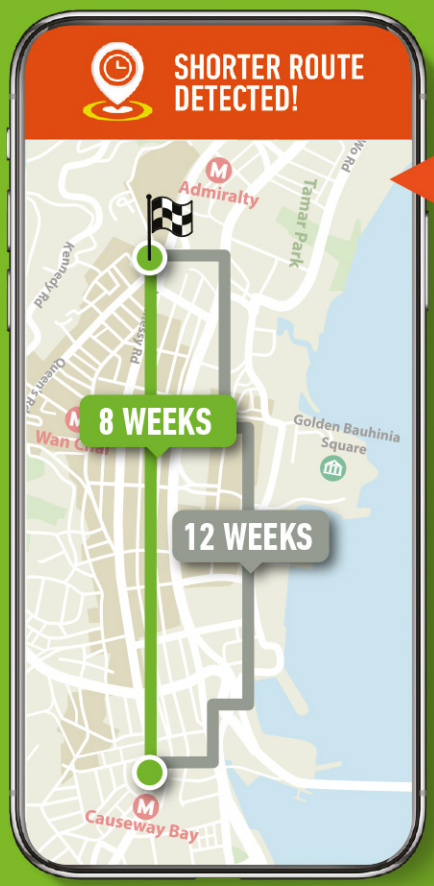

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MAVIRET® is indicated for the treatment of chronic HCV infection in adults and adolescents aged 12 to <18 years.

* SVR12, defined as HCV RNA less than the lower limit of quantification at 12 weeks after the end of treatment and was the primary endpoint in all the studies.
† Refers to GT1-6 patients, excluding decompensated cirrhotic patients and liver or kidney transplant recipients. MAVIRET® is not indicated in decompensated cirrhosis. The recommended duration of MAVIRET® is 12 weeks in liver or kidney transplant recipients, with or without cirrhosis.
‡ 2,149 HCV patients were included in a pooled analysis, whereas data were pooled from 10 phase 3 clinical trials of treatment-naïve patients with HCV GT 1-6 without cirrhosis/with compensated cirrhosis (treatment adherence analysis) and 13 phase 3 clinical trials of all patients with HCV (interruption analysis).
§ Tablets must be swallowed whole with food. Do not chew, crush, or break the tablets as this may alter the bioavailability of the agents.
ǁ Simplified treatment is recommended in treatment-naïve patients with or without compensated cirrhosis, where no RAS-testing/genotyping/subtyping is required.

AASLD=American Association for the Study of Liver Diseases. EASL=The European Association for the Study of the Liver. GT=genotype. HCV=hepatitis C virus. ITT=intention-to-treat. RAS=resistance-associated substitution. RNA=ribonucleic acid. SVR12=sustained virologic response at 12 weeks.

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References
1. MAVIRET® Hong Kong Prescribing Information 2020. **2.** Zamor PJ, et al. High sustained virologic response rates of Glecaprevir/Pibrentasvir in patients with dosing interruption or suboptimal adherence. Am J Gastroenterol. 2021;116:1896–1904. **3.** AASLD and IDSA. HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C. Available at: https://www.hcvguidelines.org/. Accessed 9 February 2022. **4.** European Association for the Study of the Liver. EASL recommendations on treatment of hepatitis C: Final update of the series. J Hepatol 2020;73:1170–1218.

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References:
1. Data on file at Baxter, available on www.stabforum.com
2. Dominique Thiveaud, et al Comparison of the performance of four elastomeric devices European Journal of Hospital Pharmacy Practice P.2 2005.

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1 Test. 34 Pathogens. ~1 Hour.

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Enterobacter cloacae complex
Escherichia coli
Haemophilus influenzae
Klebsiella aerogenes
Klebsiella oxytoca
Klebsiella pneumoniae group
Moraxella catarrhalis
Proteus spp.
Pseudomonas aeruginosa
Serratia marcescens
Staphylococcus aureus
Streptococcus agalactiae
Streptococcus pneumoniae
Streptococcus pyogenes

ATYPICAL BACTERIA
(Qualitative)
Chlamydia pneumoniae
Legionella pneumophila
Mycoplasma pneumoniae

VIRUSES
Adenovirus
Coronavirus
Human Metapneumovirus
Human Rhinovirus/Enterovirus
Influenza A
Influenza B
Middle East Respiratory Syndrome Coronavirus (MERS-CoV)
Parainfluenza Virus
Respiratory Syncytial Virus

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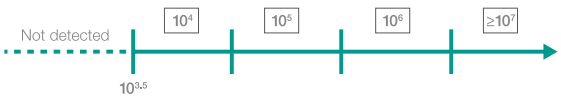
The lower respiratory tract has a complex microbiology and separating colonizing organisms from true pathogens is challenging. The BioFire Pneumonia *plus* Panel offers 15 semi-quantitative bacteria—indicating not only what pathogen is detected, but also how much is present. Organism concentrations are calculated in DNA copies/mL and rounded to the nearest whole one-log "bin," making it easier than ever to know how much organism is in a sample.[1]

Semi-quantitative bin results



SHINGRIX
(ZOSTER VACCINE
RECOMBINANT, ADJUVANTED)

Available Now

The ONLY shingles vaccine to demonstrate >90% efficacy in all age groups ≥ 50 years old.[1,2]

THE US CDC RECOMMENDS SHINGRIX AS THE PREFERRED VACCINE FOR THE PREVENTION OF SHINGLES[3]

☑ patients 50 years of age or older ☑ patients who previously received zoster vaccine (live)

Safety information[1]: SHINGRIX is indicated for prevention of herpes zoster (HZ) and post-herpetic neuralgia (PHN), in adults 50 years of age or older. For intramuscular injection only. SHINGRIX is given as a 2-dose series. The second dose can be administered as soon as 2 months after the first dose (and if necessary, anytime between 2-6 months). Most frequently reported side effects include pain at the injection site, myalgia, fatigue and headache. Most of these reactions were not long-lasting.

CDC = Centers for Disease Control and Prevention

There are limited data on vaccination with SHINGRIX in patients previously vaccinated with ZVL: In a phase 3 study, humoral immunogenicity was non inferior among subjects previously vaccinated at least 5 years earlier with ZVL. No apparent safety differences were observed between study groups within 30 days post-dose 2 of SHINGRIX. Solicited local and systemic symptoms were similar between study groups; the levels of antibodies and immune cells that correlate with protection against shingles have not been clearly defined. There are no head-to-head clinical trials comparing the efficacy and safety of SHINGRIX to ZVL[3].

Abbreviated Prescribing Information

Name of the Medicinal Product: Shingrix vaccine powder and suspension for suspension for injection. Herpes zoster vaccine (recombinant, adjuvanted) **Qualitative and Quantitative Composition:** After reconstitution, 1 dose (0.5 ml) contains 50 micrograms of gE antigen adjuvanted with AS01B, Varicella Zoster Virus (VZV) glycoprotein E (gE) produced by recombinant DNA technology in Chinese Hamster Ovarian (CHO) cells, The GlaxoSmithKline proprietary $AS01_B$ Adjuvant System is composed of the plant extract *Quillaja saponaria* Molina, fraction 21 (QS-21) (50 micrograms) and 3-O-desacyl-4'-monophosphoryllipid A (MPL) from *Salmonella minnesota* (50 micrograms) **Indications:** Shingrix is indicated for prevention of herpes zoster (HZ) and post-herpetic neuralgia (PHN), in adults 50 years of age or older. **Posology and Administration:** The primary vaccination schedule consists of two doses of 0.5 ml each: an initial dose followed by a second dose 2 months later. **Method of administration:** Intramuscular injection. **Contraindications:** Hypersensitivity to the active substances or to any component of the vaccine. **Special Warnings and Precautions for Use:** As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of an anaphylactic event following the administration of the vaccine. As with other vaccines, vaccination with Shingrix should be postponed in subjects suffering from an acute severe febrile illness. However, the presence of a minor infection, such as a cold, should not result in the deferral of vaccination. As with any vaccine, a protective immune response may not be elicited in all vaccinees. Do not administer the vaccine intravascularly or intradermally. Subcutaneous administration is not recommended. Maladministration via the subcutaneous route may lead to an increase in transient local reactions. Shingrix should be given with caution to individuals with thrombocytopenia or any coagulation disorder since bleeding may occur following intramuscular administration to these subjects. Syncope (fainting) can occur following, or even before, any vaccination as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints. **Interactions:** Shingrix can be given concomitantly with unadjuvanted inactivated seasonal influenza vaccine, 23-valent pneumococcal polysaccharide vaccine (PPV23) or reduced antigen diphtheria-tetanus-acellular pertussis vaccine (dTpa). The vaccines should be administered at different injection sites. **Fertility, pregnancy and Lactation: Pregnancy:** There are no data from the use of Shingrix in pregnant women. The effect on breast-fed infants of administration of Shingrix to their mothers has not been studied. **Undesirable effects:** lymphadenopathy, hypersensitivity reactions including rash, urticaria, angioedema, headache, gastrointestinal symptoms (including nausea, vomiting, diarrhoea and/or abdominal pain), myalgia, arthralgia, injection site reactions (such as pain, redness, swelling), fatigue, chills, fever, injection site pruritus, malaise. **Please read the full prescribing information prior to administration. Full prescribing information is available on request from GlaxoSmithKline Ltd, 23/F, Tower 6, The Gateway, 9 Canton Road, Tsimshatsui, Kowloon, Hong Kong.** Abbreviated Prescribing Information prepared in 7 Dec 2020 based on version HK052020(GDS03/EMA20200109). For adverse event reporting, please call GlaxoSmithKline Limited at (852) 3189 8989 (Hong Kong) or (853) 2871 5569 (Macau), or send an email to us at HKAdverseEvent@gsk.com.

References: 1. GSK. SHINGRIX Hong Kong Prescribing Information GDS03. **2.** MSD. Zoster live, attenuated vaccine Product Circular. **3.** Centers for Disease Control and Prevention. Recommendations of the Advisory Committee on Immunization Practices for use of herpes zoster vaccines. MMWR. 2018 Jan;67(3):103-8.

PM-HK-SGX-ADVT-210001 (052023) Date of preparation: 21/6/2021

Discover the power of SHINGRIX at gskpro.com/en-hk/

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Veklury® remdesivir 100 MG FOR INJECTION | EVERY DAY COUNTS

HELP SHORTEN TIME TO RECOVERY BY 29%

IN PATIENTS HOSPITALIZED WITH **COVID-19**, VS PLACEBO*†[1]

Indication: SARS-CoV-2 Infection‡§[2]

- VEKLURY® (n=541) significantly reduced time to recovery# by a median of 5 days compared with placebo (n=521) in the overall study population*†[1]
- Sped up recovery# by a median of 1 week vs placebo in patients who received oxygen support at baseline (11 days vs 18 days; RR: 1.31; 95% CI: 1.12—1.52)†[1]
- Shortened the period to receive oxygen by a median of 8 days (13 days vs 21 days) in patients who received oxygen support at baseline†[1]

* The median time to recovery# was 10 days for VEKLURY® but 15 days for placebo (RR for recovery: 1.29; 95% CI: 1.12–1.49; p < 0.001).[1]

† ACTT-1 was a double-blind, multicenter, randomized, placebo-controlled trial that compared the efficacy and safety of VEKLURY® and placebo in adult patients hospitalized with COVID-19 and lower respiratory tract infection. Of total 1,062 patients, they were randomly assigned in a 1:1 ratio to VEKLURY® or placebo. All received supportive care according to the standard of care for the trial site hospital. The primary outcome was the time to recovery.# The key secondary outcome was clinical status at Day 15, as assessed on the ordinal scale. Other outcomes included period with supplemental oxygen up to day 29 if it was being used at baseline.[1]

‡ Since available information on the efficacy and safety of this drug in connection with the SARS-CoV-2 infection is extremely limited, careful determination should be made as to need for administration considering the latest information.[2]

§ In line with the majority of use in clinical trials to date, in principle VEKLURY® should be used for SARS-CoV-2 infections in severe patients whose oxygen saturation of ≤ 94% (room air), requiring supplemental oxygen, under ECMO introduction, or under invasive mechanical ventilation.[2]

The primary outcome was the time to recovery, defined by either discharge from the hospital or hospitalization for infection control or other non-medical reasons. Recovery RR > 1 indicate a benefit for VEKLURY®.[1]

CI=confidence interval; COVID-19=coronavirus disease 2019; ECMO=extracorporeal membrane oxygenation; RR=rate ratio; SARS-CoV-2=severe acute respiratory syndrome coronavirus 2.

References: 1. Beigel JH, et al. N Engl J Med. 2020;383:1813–1826. **2.** VEKLURY® Hong Kong Prescribing Information. [RDV-MAY20 (v1.0)]

VEKLURY® Abbreviated Prescribing Information (Version: RDV-MAY20 v1.0)
Presentation: Veklury concentrate for solution for infusion 100 mg/20 mL: Each vial contains 100 mg of remdesivir. Colourless to clear yellow solution. Veklury powder for concentrate for solution for infusion 100 mg: Each vial contains 100 mg of remdesivir. White to off-white to yellow solid. **Indications:** SARS-CoV-2 Infection. In principle remdesivir should be used for SARS-CoV-2 infections in severe patients whose oxygen saturation of ≤ 94% (room air), requiring supplemental oxygen, under ECMO introduction, or under invasive mechanical ventilation. **Dosage:** Adults and pediatrics with body weight ≥40 kg: Single dose of remdesivir 200 mg IV injection on Day 1 followed by once-daily doses of remdesivir 100 mg IV injection from Day 2. Pediatrics with body weight between 3.5 kg and <40 kg: One dose of remdesivir 5 mg/kg IV injection on Day 1 followed by remdesivir 2.5 mg/kg IV injection from Day 2. Solution for concentrate for infusion is not recommended for pediatric between 3.5kg and <40kg. Treatment duration: While the optimal duration of treatment has not been established, as a guide, for patients who are on ECMO or invasive mechanical ventilation, the duration of treatment is up to 10 days. For patients who are not on ECMO or invasive mechanical ventilation, duration of treatment is up to 5 days or until Day 10 if no symptomatic improvement is observed. Renal impairment: Not recommended for adults, infants, children and adolescents with eGFR <30 mL/min/1.73m^2 and term newborns (7 to 28 days) with serum creatinine levels of ≥1 mg/dL. Hepatic impairment: Not recommended for patients with ALT levels ≥5 times the Upper Limit of Normal Range. Should be administered only if the therapeutic benefits outweigh the risks for patients with ALT levels are <5 times the Upper Limit of Normal Range. **Contraindications:** Hypersensitivity to the active substances or to any of the excipients. **Warnings and Precautions:** Patients should be closely monitored by appropriate clinical and laboratory monitoring during treatment with remdesivir. Laboratory values should be monitored on a daily basis. If any adverse drug reactions are observed, administration should be continued only if it is determined that the therapeutic benefits outweighs the risks. Kidney and liver function tests should be performed daily before and during administration and the patient's condition should be carefully monitored. The patient's condition should be carefully monitored for infusion reactions and administration should be immediately discontinued and appropriate measures should be taken if any abnormalities are observed. **Adverse reactions:** Information on the safety of remdesivir is extremely limited, and such information is still being collected. Clinically significant adverse reactions include acute renal impairment, hepatic impairment and infusion reactions (hypotension, nausea, vomiting, sweating and tremor). **Drug interactions:** *In vitro* studies have shown that remdesivir is a substrate for CYP2C8, CYP2D6 and CYP3A4, as well as OATP1B1 and P-gp, and, in addition, is an inhibitor of CYP3A4, OATP1B1, OATP1B3, BSEP, MRP4 and NTCP. No clinical drug-drug interaction studies have been conducted.

Before prescribing, please consult full prescribing information which is available upon request.

For medical enquiries, please send your request to asiamedinfo@gilead.com or call 800 908 348 (toll-free number)

In Hong Kong, the product is conditionally approved with very limited safety, efficacy, and quality data for public health emergency to satisfy local unmet medical need and the registration status is subjected to be reviewed by the Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial/Medicinal Test) Committee. The product can only be supplied to designated institutions.

GILEAD

Gilead Sciences Hong Kong Limited
Room 2603, 26th Floor, Hysan Place,
500 Hennessy Road, Causeway Bay,
Hong Kong

HKVEK0008_v10 4/8/2021

BIKTARVY®
bictegravir 50mg/emtricitabine 200mg/
tenofovir alafenamide 25mg tablets

THE BEAUTY OF WHAT IS POSSIBLE

BIKTARVY® is a powerful STR that combines the DESCOVY® (FTC/TAF)* backbone with bictegravir, a novel and unboosted INSTI[1,2]

DHHS & IAS RECOMMENDED
AS AN INITIAL REGIMEN FOR MOST PEOPLE WITH HIV[3,4]

EACS RECOMMENDED
AS AN INITIAL REGIMEN FOR ART-NAÏVE ADULT HIV-POSITIVE PERSONS[5]

BIKTARVY® is a small STR with once daily dosing[1,2]

- High genetic barrier to resistance
- No HLA-B 5701 testing required
- Active against HBV†
- Low potential for DDIs‡
- Once-Daily small STR§
- Taken Any Time of Day
- No Food Requirements
- No Booster

Enough said, Trusted care

Learn if BIKTARVY® is right for your patients.

The image is shown for illustration purpose only. It does not represent the actual size of the tablet.
*emtricitabine 200 mg/tenofovir alafenamide 25 mg.[1]
†BIKTARVY® contains TAF, which is active against HBV. Discontinuation of BIKTARVY® therapy in patients co-infected with HIV and HBV may be associated with severe exacerbations of hepatitis. Patients co-infected with HIV and HBV who discontinue BIKTARVY® should be closely monitored with both clinical and laboratory follow-up for at least several months after stopping treatment.[1]
‡BIKTARVY® is contraindicated with dofetilide, rifampin and St John's Wort.[1,6]
§Each BIKTARVY® tablet is approximately 15 mm x 8 mm.[1]

CrCl, creatinine clearance; DDIs, drug-drug interactions; DHHS, Department of Health and Human Services; EACS, European AIDS Clinical Society; FTC, emtricitabine; HBV, hepatitis B virus; HIV, human immunodeficiency virus; IAS, International AIDS Society; INSTI, integrase strand transfer inhibitor; PLHIV, people living with HIV; STR, single-tablet regimen; TAF, tenofovir alafenamide.

References: 1. BIKTARVY® Hong Kong Prescribing Information (HK-JUN19-EU-MAY19). **2.** Deeks ED. Bictegravir/emtricitabine/tenofovir alafenamide: A review in HIV-1 infection. Drugs 2018; 78(17): 1817-28. **3.** Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in adults and adolescents with HIV. Department of Health and Human Services. Available at: http://aidsinfo.nih.gov/contentfiles/lvguidelines/AdultandAdolescentGL.pdf. (Accessed November 21, 2020). **4.** Saag MS, Gandhi RT, Hoy JF, et al. Antiretroviral Drugs for Treatment and Prevention of HIV Infection in Adults: 2020 Recommendations of the International Antiviral Society-USA Panel. Jama 2020; 324(16): 1651-69. **5.** The EACS treatment guidelines 10.1 October, 2020. Available at: https://www.eacsociety.org/files/guidelines-10.1_5.pdf (accessed November 21, 2020). **6.** Di Perri G. Clinical pharmacology of the single tablet regimen bictegravir/emtricitabine/ tenofovir alafenamide (BIC/FTC/TAF). Infez Med 2019; 27(4): 365-73.

BIKTARVY® Abbreviated Prescribing Information (Version: HK-JUN19-EU-MAY19)
Presentation: Each film-coated tablet contains bictegravir sodium equivalent to 50 mg of bictegravir, 200 mg of emtricitabine, and tenofovir alafenamide fumarate equivalent to 25 mg of tenofovir alafenamide. Purplish-brown, capsule-shaped, film-coated tablet debossed with "GSI" on one side and "9883" on the other side of the tablet. Each tablet is approximately 15 mm x 8 mm. **Indications:** Biktarvy is indicated for the treatment of adults infected with human immunodeficiency virus-1 (HIV-1) without present or past evidence of viral resistance to the integrase inhibitor class, emtricitabine or tenofovir. **Dosage:** Adults: One tablet to be taken once daily with or without food. Elderly: No dose adjustment is required. Renal impairment: No dose adjustment for patients with estimated creatinine clearance (CrCl)≥ 30mL/min. Not recommended in patients with estimated CrCl below 30 mL/min. Hepatic impairment: No dose adjustment for patients with mild or moderate hepatic impairment (Child-Pugh-Turcotte [CPT] Class A or B). Not recommended in patients with severe hepatic impairment (CPT Class C). Paediatric population: The safety and efficacy in children and adolescents aged less than 18 years not yet been established. **Contraindications:** Hypersensitivity to the active substances or to any of the excipients. Co-administration with rifampicin and St John's Wort (*Hypericum perforatum*). **Warnings and Precautions:** Patients co-infected with HIV and hepatitis B or C virus: Patients with chronic hepatitis B or C treated with antiretroviral therapy are at an increased risk for severe and potentially fatal hepatic adverse reactions. Discontinuation of Biktarvy therapy in patients co-infected with HIV and HBV may be associated with severe acute exacerbations of hepatitis. Patients co-infected with HIV and HBV who discontinue Biktarvy should be closely monitored with both clinical and laboratory follow-up for at least several months after stopping treatment. Liver disease: Patients with pre-existing liver dysfunction, including chronic active hepatitis, have an increased frequency of liver function abnormalities during combination antiretroviral therapy (CART) and should be monitored according to standard practice. If there is evidence of worsening liver disease in such patients, interruption or discontinuation of treatment must be considered. Weight and metabolic parameters: An increase in weight and in levels of blood lipids and glucose may occur during antiretroviral therapy. Lipid disorders should be managed as clinically appropriate. Mitochondrial dysfunction following exposure in utero: Nucleos(t)ide analogues may impact mitochondrial function to a variable degree. The findings do not affect current national recommendations to use antiretroviral therapy in pregnant women to prevent vertical transmission of HIV. Immune Reactivation Syndrome: In HIV infected patients with severe immune deficiency at the time of institution of CART, an inflammatory reaction to asymptomatic or residual opportunistic pathogens may arise and cause serious clinical conditions, or aggravation of symptoms. Any inflammatory symptoms should be evaluated and treatment instituted when necessary. Autoimmune disorders have also been reported. Opportunistic infections: Patients should remain under close clinical observation by physicians experienced in the treatment of patients with HIV associated diseases. Osteonecrosis: Patients should be advised to seek medical advice if they experience joint aches and pain, joint stiness or diculty in movement. Nephrotoxicity: A potential risk of nephrotoxicity resulting from chronic exposure to low levels of tenofovir due to dosing with tenofovir alafenamide cannot be excluded. Co-administration of other medicinal products: Biktarvy should be administered at least 2 hours before, or with food 2 hours after antacids containing magnesium and/or aluminium. Biktarvy should be administered at least 2 hours before iron supplements, or taken together with food. Biktarvy should not be co-administered with other antiretroviral medicinal products. **Adverse reactions:** Most frequently reported adverse reactions were headache, diarrhoea and nausea. Please refer to full prescribing information for full list of adverse reactions. **Drug interactions:** Interactions between Biktarvy and other medicinal products: St. John's wort, rifampicin, rifabutin, rifapentine, atazanavir 3 cobicistat, boceprevir, azithromycin, clarithromycin, carbamazepine, oxcarbazepine, phenobarbital, phenytoin, magnesium/ aluminiumcontaining antacid suspension, ferrous fumarate, sucralfate, ciclosporin, methadone and metformin.

Before prescribing, please consult full prescribing information which is available upon request.

For medical enquiries, please send your request to asiamedinfo@gilead.com or call 800 908 348 (toll-free number).
HKBIK0092_v1.0 2/17/2021

GILEAD | HIV

Gilead Sciences Hong Kong Limited
Room 2603, 26th Floor, Hysan Place
500 Hennessy Road, Causeway Bay, Hong Kong

Indication: DELSTRIGO® is indicated for the treatment of adults infected with HIV-1 without past or present evidence of resistance to the NNRTI class, lamivudine, or tenofovir[3]

Abbreviations: ART: Antiretroviral therapy; CVD: Cardiovascular disease; HIV: Human immunodeficiency virus; RNA: Ribonucleic acid; NNRTI: Non-nucleoside reverse transcriptase inhibitor

References: 1. Kumar P, *et al.* Switching to DOR/3TC/TDF Maintains HIV-1 Virologic Suppression Through Week 144 in the DRIVE-SHIFT Trial. *J Acquir Immune Defic Syndr* 2021;87:801–805
2. European AIDS Clinical Society. EACS Guidelines. October 2021. Version 11.0. **3.** Delstrigo Hong Kong Product Circular.

Delstrigo Selected Safety Information

Indications: Delstrigo (doravirine 100 mg/lamivudine 300 mg/tenofovir disoproxil fumarate 300mg) is indicated for the treatment of adults infected with HIV-1 without past or present evidence of resistance to the NNRTI class, lamivudine, or tenofovir.

Contraindications: • Hypersensitivity to the active substances or to any of the excipients. Co-administration with medicinal products that are strong cytochrome P450 (CYP)3A enzyme inducers is contraindicated as significant decreases in doravirine plasma concentrations are expected to occur. For the list of contraindicated medicines, please consult the full prescribing information.

Precautions: • NNRTI substitutions and use of doravirine - Doravirine has not been evaluated in patients with previous virologic failure to any other antiretroviral therapy. There is not sufficient clinical evidence to support the use of doravirine in patients infected with HIV-1 with evidence of resistance to the NNRTI class. • Severe acute exacerbation of hepatitis B in patients co-infected with HIV-1 and HBV - All patients with HIV-1 should be tested for the presence of hepatitis B virus (HBV) before initiating antiretroviral therapy. Patients who are co-infected with HIV-1 and HBV should be closely monitored with both clinical and laboratory follow-up for at least several months after stopping treatment with Delstrigo. • New onset or worsening renal impairment - Delstrigo should be avoided with concurrent or recent use of nephrotoxic medicinal products (e.g., high-dose or multiple NSAIDs). Persistent or worsening bone pain, pain in extremities, fractures, and/or muscular pain or weakness may be manifestations of proximal renal tubulopathy and should prompt an evaluation of renal function in at risk patients. • Bone loss and mineralisation defects - The effects of tenofovir disoproxil associated changes in BMD and biochemical markers on long-term bone health and future fracture risk are unknown. Assessment of BMD should be considered for HIV-1 infected adult patients who have a history of pathologic bone fracture or other risk factors for osteoporosis or bone loss. • Co-administration with other antiviral products - Doravirine/lamivudine/tenofovir disoproxil must not be co-administered with other medicinal products containing lamivudine, or with medicinal products containing tenofovir disoproxil, or tenofovir alafenamide, or with adefovir dipivoxil • Use with CYP3A inducers - Caution should be given to prescribing doravirine with medicinal products that may reduce the exposure of doravirine • Immune reactivation syndrome - Immune reactivation syndrome has been reported in patients treated with combination antiretroviral therapy.
• Lactose - Delstrigo contains lactose monohydrate. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Adverse events: • The most frequently reported adverse reactions considered possibly or probably related to doravirine were nausea (4%) and headache (3%). Other common adverse events (≥1% to <10%) associated with doravirine/lamivudine/tenofovir disoproxil include abnormal dreams, insomnia, headache, dizziness, somnolence, cough, nasal symptoms, nausea, diarrhoea, abdominal pain, vomiting, flatulence, alopecia, rash, muscle disorders, fatigue, fever and alanine aminotransferase increased. For detailed side effects, please consult the full prescribing information.

Drug interactions: Delstrigo is a complete regimen for the treatment of HIV-1 infection; therefore, Delstrigo should not be administered with other antiretroviral medicinal products. *Effects of other medicinal products on doravirine, lamivudine, and tenofovir disoproxil* • Doravirine - Doravirine is primarily metabolised by CYP3A, and medicinal products that induce or inhibit CYP3A are expected to affect the clearance of doravirine • Lamivudine - Because lamivudine is primarily eliminated by the kidneys through a combination of glomerular filtration and active tubular secretion, co-administration of doravirine/lamivudine/tenofovir disoproxil with medicinal products that reduce renal function or compete for active tubular secretion may increase serum concentrations of lamivudine. • Tenofovir disoproxil - Because tenofovir is primarily eliminated by the kidneys through a combination of glomerular filtration and active tubular secretion, co-administration of doravirine/lamivudine/tenofovir disoproxil with medicinal products that reduce renal function or compete for active tubular secretion via OAT1, OAT3 or MRP4 may increase serum concentrations of tenofovir. *Effects of doravirine, lamivudine, and tenofovir disoproxil on other medicinal products* • Doravirine - Doravirine at a dose of 100 mg once daily is not likely to have a clinically relevant effect on the plasma concentrations of medicinal products that are dependent on transport proteins for absorption and/or elimination or that are metabolised by CYP enzymes. • Lamivudine - Lamivudine does not inhibit or induce CYP enzymes. • Tenofovir - Based on the results of in vitro experiments and the known elimination pathway of tenofovir, the potential for CYP-mediated interactions involving tenofovir with other medicinal products is low. **Before prescribing, please consult the full prescribing information.**

MSD

Merck Sharp & Dohme (Asia) Ltd.
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Tel: (852) 3971 2800 Fax: (852) 2834 0756
Website: www.msd.com.hk

HK-DOR-00075 Jun/2022

Pfizer

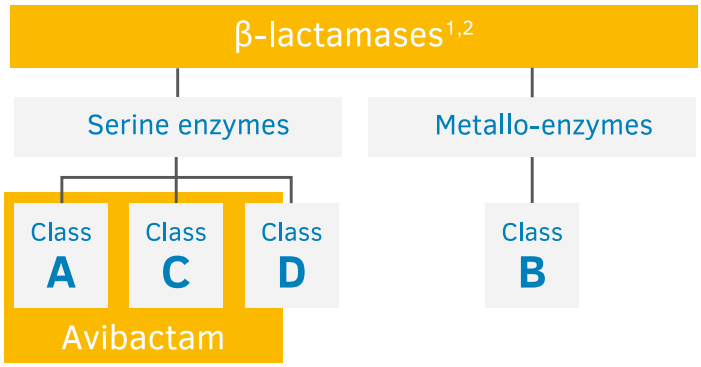
ZAVICEFTA™
ceftazidime and avibactam

Novel Agent Against Gram Negative Resistant Pathogens

Indicated for[1]

- Complicated intra-abdominal infection
- Complicated urinary tract infection, including pyelonephritis
- Hospital-acquired pneumonia, including ventilator-associated pneumonia

Novel β-Lactamases Inhibitor with Breakthrough Inhibition[1,2]



Avibactam inhibits both Ambler class A and class C β-lactamases and some class D enzymes, including :[1]*

• ESBLs • KPCs • OXA-48 carbapenemases • AmpC enzymes

* Avibactam does not inhibit class B enzymes (metallo-β-lactamases) and is not able to inhibit many class D enzymes.[1]
ESBL, extended-spectrum β-lactamase; KPC, Klebsiella pneumoniae carbapenemase.

ZAVICEFTA ABBREVIATED PACKAGE INSERT

1. TRADE NAME: ZAVICEFTA 2. PRESENTATION: Powder for concentrate for solution for infusion 2g ceftazidime/0.5g avibactam **3. INDICATIONS:** Indicated in adults for: (a) complicated intra-abdominal infection (cIAI); (b) complicated urinary tract infection (cUTI), including pyelonephritis; (c) hospital-acquired pneumonia (HAP), including ventilator associated pneumonia (VAP) **4. DOSAGE:** 2.5g Q8H for 2 hours. Refer to full PI for duration of therapy. **5. CONTRAINDICATIONS:** Hypersensitivity to active substances, to any of the excipients or to any cephalosporin antibacterial agent. Severe hypersensitivity (e.g., anaphylactic reaction, severe skin reaction) to any other type of β-lactam antibacterial agent (e.g., penicillins, monobactams or carbapenems) **6. WARNINGS & PRECAUTIONS:** Hypersensitivity reactions; clostridium difficile-associated diarrhea; in patients with renal impairment; nephrotoxicity; direct antiglobulin test (DAGT or COOMBs test) seroconversion and potential risk of haemolytic anaemia; in patients with controlled sodium diet. Ceftazidime may interfere with copper reduction methods (Benedict's, Fehling's, Clinitest) for detection of glycosuria leading to false-positive results. Ceftazidime does not interfere with enzyme-based tests for glycosuria. **(Please refer to the full Prescribing Information for details) 7. INTERACTIONS:** Probenecid and chloramphenicol. Concurrent treatment with high doses of cephalosporins and nephrotoxic medicinal products such as aminoglycosides or potent diuretics (e.g., furosemide) may adversely affect renal function. **8. PREGNANCY AND LACTATION:** Should only be used during pregnancy only if the potential benefit outweighs the possible risk. Ceftazidime is excreted in human milk in small quantities and a decision must be made whether to discontinue breast feeding or to discontinue/abstain from ceftazidime/avibactam therapy taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman. **9. SIDE EFFECTS: Very Common:** Coombs direct test positive. **Common:** Candidiasis (including vulvovaginal candidiasis and oral candidiasis), eosinophilia, thrombocytosis, thrombocytopenia, headache, dizziness, diarrhea, abdominal pain, nausea, vomiting, alanine aminotransferase increased, aspartate aminotransferase increased, blood alkaline phosphatase increased, gammaglutamyltransferase increased, blood lactate dehydrogenase increased, rash maculopapular, urticaria, pruritus, infusion site thrombosis, infusion site phlebitis, pyrexia. Reference: HK PI (version date/LPD date) OCT 2018 Date of preparation: MAR2019 Identifier number: ZAVI0319

FULL PRESCRIBING INFORMATION IS AVAILABLE UPON REQUEST.

References: 1. Zavicefta™ (Ceftazidime-avibactam) Prescribing Information. Pfizer Corporation Hong Kong Limited Version October 2018
2. Liscio JL, *et al. Int J Antimicrob Agents* 2015;46:266–71

Pfizer
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Tel: (852) 2811 9711 Fax: (852) 2579 0599
Website: www.pfizer.com.hk

PP-ZVA-HKG-0032 01/2021

MSD

TAKE ON THE CHALLENGES OF COVID-19[1]

TEST. TREAT. TAKE CHARGE.

molnupiravir

Reference: 1. molnupiravir US EUA Product Insert.

MOLNUPIRAVIR Selected Safety Information

Authorized Use

1. Molnupiravir is authorized for use under an Emergency Use Authorization (EUA) for the treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in adults:
   - with positive results of direct SARS-CoV-2 viral testing, and
   - who are at high risk for progression to severe COVID-19, including hospitalization or death, and
   - for whom alternative COVID-19 treatment options approved or authorized by FDA are not accessible or clinically appropriate
2. Molnupiravir is not approved for any use, including the treatment of COVID-19, but is authorized for emergency use by the FDA under an Emergency Use Authorization (EUA).
3. The emergency use of molnupiravir is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1) unless the declaration is terminated or authorization revoked sooner.

Limitations of Authorized Use

4. Molnupiravir is not authorized:
   - for use in patients who are less than 18 years of age
   - for initiation of treatment in patients hospitalized due to COVID-19. Benefit of treatment with molnupiravir has not been observed in subjects when treatment was initiated after hospitalization due to COVID-19
   - for use for longer than 5 consecutive days
   - or pre-exposure or post-exposure prophylaxis for prevention of COVID-19
5. Molnupiravir may only be prescribed for an individual patient by physicians, advanced practice registered nurses, and physician assistants that are licensed or authorized under state law to prescribe drugs in the therapeutic class to which molnupiravir belongs (i.e., anti-infectives).

Contraindications

6. No contraindications have been identified based on the limited available data on the emergency use of molnupiravir authorized under this EUA.

Warnings and Precautions

7. There are limited clinical data available for molnupiravir. Serious and unexpected adverse events may occur that have not been previously reported with molnupiravir use.
8. Molnupiravir is not recommended for use during pregnancy. Based on findings from animal reproduction studies, molnupiravir may cause fetal harm when administered to pregnant individuals. There are no available human data on the use of molnupiravir in pregnant individuals to evaluate the risk of major birth defects, miscarriage or adverse maternal or fetal outcomes.
9. Molnupiravir is authorized to be prescribed to a pregnant individual only after the healthcare provider has determined that the benefits would outweigh the risks for that individual patient. If the decision is made to use molnupiravir during pregnancy, the prescribing healthcare provider must document that the known and potential benefits and the potential risks of using molnupiravir during pregnancy were communicated to the pregnant individual.
10. Advise individuals of childbearing potential of the potential risk to a fetus and to use an effective method of contraception correctly and consistently during treatment with molnupiravir and for 4 days after the final dose.
11. Prior to initiating treatment with molnupiravir, assess whether an individual of childbearing potential is pregnant or not, if clinically indicated.
12. Hypersensitivity reactions, including anaphylaxis, have been reported with molnupiravir. If signs and symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, immediately discontinue molnupiravir and initiate appropriate medications and/or supportive care.
13. Molnupiravir is not authorized for use in patients less than 18 years of age because it may affect bone and cartilage growth. The safety and efficacy of molnupiravir have not been established in pediatric patients.

Adverse Reactions

14. The most common adverse reactions occurring in ≥1% of subjects in the molnupiravir treatment group in the Phase 3 double-blind MOVe-OUT study were diarrhea (2% versus placebo at 2%),nausea (1% versus placebo at 1%), and dizziness (1% versus placebo at 1%) all of which were Grade 1 (mild) or Grade 2 (moderate). Serious adverse events occurred in 7% of subjects receiving molnupiravir and 10% receiving placebo; most serious adverse events were COVID-19 related. Adverse events leading to death occurred in 2 (<1%) of the subjects receiving molnupiravir and 12 (2%) of subjects receiving placebo.

Drug Interactions

15. No drug interactions have been identified based on the limited available data on the emergency use of molnupiravir. No clinical drug-drug interaction trials of molnupiravir with concomitant medications, including other treatments for mild to moderate COVID-19, have been conducted.

Breastfeeding

16. There are no data on the presence of molnupiravir or its metabolites in human milk. It is unknown whether molnupiravir has an effect on the breastfed infant or effects on milk production. Based on the potential for adverse reactions in the infant from molnupiravir, breastfeeding is not recommended during treatment with molnupiravir and for 4 days after the final dose. A lactating individual may consider interrupting breastfeeding and may consider pumping and discarding breast milk during treatment and for 4 days after the last dose of molnupiravir.

Males of Reproductive Potential

17. Nonclinical studies to fully assess the potential for molnupiravir to affect offspring of treated males have not been completed. Advise sexually active individuals with partners of childbearing potential to use a reliable method of contraception correctly and consistently during treatment and for at least 3 months after the last dose of molnupiravir. The risk beyond three months after the last dose of molnupiravir is unknown.

Before prescribing, please consult the full prescribing information.

MSD

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Website: www.msd.com.hk

HK-ANV-00009 May/2022

Flublok®
QUADRIVALENT
Influenza Vaccine

APPROVED FOR PATIENTS 18+

A NEW Recombinant Influenza Vaccine that offers

- **30%** Better Protection in 50 yo+*[1,2]
- **44.6%** Cross Protection for any virus strain^[3]

*VS standard dose

^ regardless of match to vaccine

2017 FDA approved[4]

Consistent match to predicted strains[1,5]

Egg-free[1]

MAT-HK-2200045-1.0-01/2022

Presentation: Quadrivalent influenza vaccine (recombinant, prepared in cell culture), solution for injection in pre-filled syringe. **Indications:** For active immunization for the prevention of influenza disease in adults. **Dosage & Administration:** One dose of 0.5 mL. For intramuscular injection only. Preferred site is in the deltoid muscle. Must not be injected intravascularly and must not be mixed with other vaccines in the same syringe. **Contraindications:** Below 18 years of age. Hypersensitivity to active substances, to any of the excipients or to any trace residuals such as octylphenol ethoxylate. **Precautions:** Appropriate medical treatment and supervision be available in case of an anaphylactic event. Postpone vaccination in patients with acute febrile illness until the fever is resolved. Antibody response in patients with endogenous or iatrogenic immunosuppression may be insufficient to prevent influenza. Flublok must be administered with caution to individuals with thrombocytopaenia or a bleeding disorder since bleeding may occur following an intramuscular administration. Procedures should be in place to prevent falling and injury and to manage syncope. **Drug Interactions:** If Flublok is to be given at the same time as another injectable vaccine, the vaccines should always be administered at different injection sites. **Pregnancy and lactation:** Assessment of risks and benefits should be performed by an HCP before administering Flublok to a pregnant or breast-feeding woman. It is not known whether Flublok vaccine is excreted in human milk. **Undesirable effects:** Most common reactions reported: Injection-site reactions (tenderness and pain). Other very common and common adverse reactions reported: Headache, Fatigue, Myalgia, Arthralgia, Nausea, Firmness/ Swelling, Redness, Fever, Shivering/ Chills. For other undesirable effects, please refer to the full prescribing information. **Preparation:** 1 x 0.5 mL in pre-filled syringe without needle, 10 x 0.5 mL in pre-filled syringe without needle, 1 x 0.5 mL in pre-filled syringe with separate needle. **Legal Classification:** Part 1, First & Third Schedules Poison ***Full prescribing information is available upon request.***

APL-HK-FLB-21.04

Sanofi Pasteur HCP Portal

Reference:

1. Flublok® Quadrivalent (Influenza Vaccine) [Prescribing Information]. 2. Dunkle LM, Izikson R, Patriarca P, et al. Efficacy of recombinant influenza vaccine in adults 50 years of age or older. N Engl J Med. 2017;376:2427-2436. 3. Treanor JJ, et. al. Vaccine. 2011;29(44):7733-7739 (PSC04). 4. FDA. https://www.fda.gov/vaccines-blood-biologics/vaccines/flublok Accessed on 14Jan2022 5. US CDC. https://www.cdc.gov/flu/prevent/how-fluvaccine-made.htm Accessed on 14Jan2022

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SANOFI PASTEUR

IMOJEV®

(live-attenuated Japanese encephalitis vaccine)

For individual aged 9 months and above to protect them from Japanese encephalitis[2]

*WHO recommends **Japanese encephalitis virus vaccination** as an effective way to prevent infection[1]*

Give your patients the best and don't let Japanese encephalitis strip them of their childhood joy

1. World Health Organization, Japanese Encephalitis Vaccines: WHO position paper – February 2015. Weekly epidemiological record 2015;90(9):69-88
2. Imojev Package Insert, Sep 2016 Version.

MAT-HK-2000099-1.0-06/2020

Presentation: Live attenuated Japanese Encephalitis Vaccine, powder and diluent for suspension for injection. **Indications**: For prophylaxis of Japanese encephalitis caused by the Japanese encephalitis virus, in individuals from 9 months of age and over. **Dosage:** Primary vaccination: Individuals 9 months of age and over: A 0.5 mL single injection. Booster: Adult population (18 years of age and over): There is no need for a booster dose up to 5 years after the administration of a single dose of IMOJEV. Paediatric population (9 months to 17 years of age inclusive): One booster dose for long term protection, given preferably 12 months after primary vaccination and can be given up to 24 months after primary vaccination. Safety and efficacy of a booster dose in children and adolescents 5 to 17 years of age have not been established. Administered subcutaneously. For details of the dosage and administration, please refer to the full prescribing information. **Contraindications:** Anyone with a history of severe allergic reaction to any component of the vaccine or after previous administration of the vaccine or a vaccine containing the same components or constituents. Vaccination must be postponed in case of febrile or acute disease. Congenital or acquired immune deficiency impairing cellular immunity, including immunosuppressive therapies such as chemotherapy, high doses of systemic corticosteroids given generally for 14 days or more. Individuals with symptomatic HIV infection or with asymptomatic HIV infection when accompanied by evidence of impaired immune function. **Precautions:** Appropriate medical treatment and supervision should always be readily available in case of a rare anaphylactic event following administration of the vaccine. Allergic to any component of the vaccine. Experienced allergic reactions or neurological disorders further to a previous vaccine injection. *For details of the precautions, please refer to the full prescribing information.* **Interactions:** In adults, IMOJEV may be administered at the same time as yellow fever vaccine using separate syringes, and into separate limbs. In children, IMOJEV may be administered at the same time as measles vaccine, either stand alone or combined with mumps and/or rubella vaccines, from as early as 9 months of age. **Fertility, pregnancy and lactation:** No fertility data are available in humans. IMOJEV must not be administered to pregnant women. Women of childbearing age should be advised not to become pregnant for 4 weeks after vaccination. IMOJEV vaccination is contraindicated in breastfeeding women. **Undesirable effects:** *Systemic reactions most frequently reported in adults:* headache, fatigue, malaise and myalgia. *Injection site reactions most frequently reported in adults:* Injection site pain. *Systemic Reactions most frequently reported: Children (2 to 5 years):* Malaise, fever, headache and myalgia. *Toddlers (12 to 24 months):* Fever, appetite lost and irritability. *Injection site reactions most frequently reported:* Injection site pain/tenderness and injection site erythema. *For details of the undesirable effects, please refer to the full prescribing information.* **Storage:** Store in a refrigerator (2°C - 8°C). Do not freeze. **Preparation:** 1 vial of vaccine powder (single dose) + 1 vial of diluent (single dose) + 1 syringe and 2 separate needles per box. **Legal Classification:** Part 1, First & Third Schedules Poison ***Full prescribing information is available upon request.***
API-HK-JEV-17.04

VACCINE HUB
GET THE FACTS ON IMMUNISATION

Vaccinehubhk

For Healthcare Professionals Only

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SANOFI PASTEUR

Dovato
dolutegravir/lamivudine

POWER REIMAGINED

AN INNOVATIVE NEW TREATMENT FOR YOUR PATIENTS LIVING WITH HIV

POWERED BY DOLUTEGRAVIR AT THE CORE

DURABLE, NON-INFERIOR EFFICACY WITH 0 RESISTANCE vs A 3-DRUG REGIMEN[1]

FEWER ANTIRETROVIRALS vs A 3-DRUG REGIMEN: **TDF, TAF** AND **ABC FREE**[2]

GEMINI-1 and GEMINI-2 96-week data in treatment-naïve patients:
DOVATO 86.0% (n=716) vs DTG + TDF/FTC 89.5% (n=717)
(Proportion of patients with HIV-1 RNA <50 copies/mL)

DTG 50 mg + 3TC 300 mg used in the GEMINI studies.

Dovato indicated as a complete regimen for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults with no antiretroviral treatment history and with no known substitutions associated with resistance to the individual components of Dovato[2].

Abbreviated prescribing information

Dovato Each film-coated tablet contains 50 mg dolutegravir, 300 mg lamivudine. **Therapeutic indication:** Indicated as a complete regimen for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults with no antiretroviral treatment history and with no known substitutions associated with resistance to the individual components of Dovato. **Posology and method of administration:** Therapy should be prescribed by a physician experienced in the management of HIV infection. Oral use. Can be taken with or without food. *Adults:* Dovato one 50 mg/300 mg tablet once daily. A separate preparation of dolutegravir is available where a dose adjustment is indicated due to drug-drug interactions (e.g. rifampicin, carbamazepine, oxcarbazepine, phenytoin, phenobarbital, St. John's wort, etravirine (without boosted protease inhibitors), efavirenz, nevirapine, or tipranavir/ritonavir). In these cases the physician should refer to the individual product information for dolutegravir. *Women of childbearing potential (WOCBP)* should undergo pregnancy testing before initiation of Dovato. WOCBP who are taking Dovato should use effective contraception throughout treatment. *Missed doses:* Take Dovato as soon as possible, providing the next dose is not due within 4 hours. If the next dose is due within 4 hours, the patient should not take the missed dose and simply resume the usual dosing schedule. *Elderly:* There are limited data available on the use of Dovato in patients aged 65 years and over. No dose adjustment is necessary. *Renal impairment:* Dovato is not recommended for use in patients with a creatinine clearance < 50 mL/min. No dose adjustment is required in patients with mild renal impairment. *Hepatic impairment:* No dosage adjustment is required in patients with mild or moderate hepatic impairment (Child-Pugh grade A or B). No data are available in patients with severe hepatic impairment (Child-Pugh grade C); therefore Dovato should be used with caution in these patients. *Paediatric population:* The safety and efficacy of Dovato in paediatric patients have not been established. **Contraindications:** Hypersensitivity to the active substances or to any of the excipients. **Warnings & precautions:** *Transmission of HIV:* Precautions to prevent transmission should be taken in accordance with national guidelines. *Hypersensitivity reactions:* Discontinue Dovato and other suspect medicinal products immediately if signs or symptoms of hypersensitivity reactions develop (including, but not limited to, severe rash or rash accompanied by raised liver enzymes, fever, general malaise, fatigue, muscle or joint aches, blisters, oral lesions, conjunctivitis, facial oedema, eosinophilia, angioedema). Monitor clinical status including liver aminotransferases and bilirubin. Delay in stopping treatment with Dovato or other suspect active substances after the onset of hypersensitivity may result in a life-threatening allergic reaction. *Weight and metabolic parameters:* An increase in weight and in levels of blood lipids and glucose may occur during antiretroviral therapy. Monitor blood lipids and glucose reference according to established HIV treatment guidelines. Lipid disorders should be managed as clinically appropriate. *Liver disease:* If Dovato is used in patients co-infected with hepatitis B an additional antiviral is therefore generally needed. If Dovato is discontinued in patients co-infected with hepatitis B virus, periodic monitoring of both liver function tests and markers of HBV replication is recommended, as withdrawal of lamivudine may result in an acute exacerbation of hepatitis. Patients with preexisting liver dysfunction should be monitored according to standard practice. If there is evidence of worsening liver disease in such patients, interruption or discontinuation of treatment must be considered. *Immune Reactivation Syndrome:* Any inflammatory symptoms should be evaluated and treatment instituted when necessary. *Mitochondrial dysfunction following exposure in utero:* There have been reports of mitochondrial dysfunction in HIV-negative infants exposed in utero and/or post-natally to nucleoside analogues. Some late-onset neurological disorders have been reported rarely. These findings should be considered for any child exposed in utero to nucleoside and nucleotide analogues, who presents with severe clinical findings of unknown aetiology. *Osteonecrosis:* Patients should be advised to seek medical advice if they experience joint aches and pain, joint stiffness or difficulty in movement. *Opportunistic infections:* Patients remain under close clinical observation of these associated HIV diseases by physicians. *Drug interactions:* The recommended dose of dolutegravir is 50 mg twice daily when co-administered with rifampicin, carbamazepine, oxcarbazepine, phenytoin, phenobarbital, St. John's wort, etravirine (without boosted protease inhibitors), efavirenz, nevirapine, or tipranavir/ritonavir. Dovato should not be co-administered with polyvalent cation-containing antacids. Polyvalent cation-containing antacids are recommended to be taken 2 hours after or 6 hours before Dovato. When taken with food, Dovato and supplements or multivitamins containing calcium, iron or magnesium can be taken at the same time. If Dovato is administered under fasting conditions, supplements or multivitamins containing calcium, iron or magnesium are recommended to be taken 2 hours after or 6 hours before Dovato. A dose adjustment of metformin should be considered when starting and stopping coadministration of Dovato with metformin, to maintain glycaemic control. The combination of Dovato with cladribine is not recommended. Dovato should not be taken with any other medicinal product containing dolutegravir or lamivudine, except where a dose adjustment of dolutegravir is indicated due to drug-drug interactions. **Interactions:** Dolutegravir is eliminated mainly through metabolism by uridine diphosphate glucuronosyl transferase (UGT) 1A1. Dolutegravir is also a substrate of UGT1A3, UGT1A9, CYP3A4, P-glycoprotein (P-gp), and breast cancer resistance protein (BCRP). Co-administration of Dovato and other medicinal products that inhibit UGT1A1, UGT1A3, UGT1A9, CYP3A4, and/or P-gp may, therefore, increase dolutegravir plasma concentration. Medicinal products that induce those enzymes or transporters may decrease dolutegravir plasma concentration and reduce the therapeutic effect of dolutegravir. Lamivudine is cleared renally. Active renal secretion of lamivudine in the urine is mediated through the organic cation transporter (OCT) 2 and multidrug and toxin extrusion transporters (MATE1 and MATE2-K). **Pregnancy & lactation:** The safety and efficacy of a dual regimen has not been studied in pregnancy. Dovato use during pregnancy only if the expected benefit justifies the potential risk to the foetus. Not recommend HIV infected women to breast-feed their infants under any circumstances in order to avoid transmission of HIV. No data on effects on human fertility. **Adverse reactions:** Very common: headache, nausea, diarrhoea; Common: depression, anxiety, insomnia, abnormal dreams, dizziness, somnolence, vomiting, flatulence, abdominal pain/discomfort, rash, pruritus, alopecia, arthralgia, muscle disorders (including myalgia), fatigue, creatine phosphokinase (CPK) elevations, alanine aminotransferace (ALT) and/or aspartate aminotransferace (AST) elevations. **Overdose:** No specific treatment for overdose. Patient should be treated supportively with appropriate monitoring as necessary.

Safety information: Overall AE profiles were similar. There was a lower risk of drug-related AEs in the Dovato arm at week 96.

Please read the full prescribing information prior to administration. Full prescribing information is available on request from GlaxoSmithKline Ltd, 23/F, Tower 6, The Gateway, 9 Canton Road, Tsimshatsui, Kowloon, Hong Kong. Abbreviated Prescribing Information based on PI version HK122019 GDS01/EU20190701 For adverse events reporting, please call GlaxoSmithKline Limited at (852) 3189 8989 (Hong Kong) or (853) 2871 5569 (Macau) or email to HK Adverse Event mailbox: HKAdverseEvent@gsk.com

Reference: 1. Cahn P et al. Presented at: International AIDS Conference; July 21-24, 2019; Mexico City, Mexico. Slides WEAB0404LB. **2.** Dovato Full Prescribing Information, HK122019.

WORKING ON BEHALF OF ViiV HEALTHCARE IN HIV

GlaxoSmithKline Limited
23/F, Tower 6, The Gateway, 9 Canton Road, TsimShaTsui, Kowloon, Hong Kong
Tel: (852) 3189 8989 Fax: (852) 3189 8931

PM-HK-DLT-ADVT-200001
Date of preparation: 13/04/2021 (04/23)

LIBERATE YOUR PATIENTS FROM DAILY HIV THERAPY

with VOCABRIA + REKAMBYS, the first and only, complete long-acting injectable regimen, dosed once every 2 months, for virologically suppressed* patients[1,2]

First and only, complete long-acting regimen for HIV-1[1,2]

The efficacy you have come to expect from daily HIV regimens[1]

Preferred by 98% of patients over daily oral therapy in the ATLAS-2M clinical trial[3]

At Week 48, 98% of 306 patients with no prior exposure to VOCABRIA + REKAMBYS who responded to the questionnaire preferred every 2-month injections vs 1% of 306 patients who preferred the study daily oral lead-in (1% reported no preference).[3]

VOCABRIA cabotegravir suspension for injection + REKAMBYS rilpivirine suspension for injection

*HIV-1 RNA <50 copies/mL[1] in adults who are virologically suppressed (HIV-1 RNA <50 copies/mL) on a stable antiretroviral regimen without present or past evidence of viral resistance to, and no prior failure with agents of NNRTI and INI class.

Vocabria (cabotegravir 30mg film-coated tablets and 600mg prolonged-release suspension for injection in 3mL), and Rekambys (rilpivirine 900mg prolonged-release suspension for injection in 3mL).
Important Safety Information
Contraindications: • Hypersensitivity to any ingredient • Coadministration with rifampicin, rifapentine, rifabutin, phenytoin, phenobarbital, carbamazepine, oxcarbazepine, systemic dexamethasone (except single dose) • St John's Wort **Warnings and Precautions:** • If discontinued, adopt a fully suppressive antiretroviral regimen no later than when the next injection would have been due • If virologic failure is suspected an alternative regimen should be adopted as soon as possible. Residual concentrations may remain for prolonged periods after discontinuation. • Increased risk of failure associated with 2 or more of: archived rilpivirine resistance mutations BMI 30 kg/m2 or HIV-1 A6/A1 subtype • Caution if uncertain treatment history without pre-treatment resistance analyses, if BMI 30 kg/m2, or HIV-1 A6/A1 subtype • Hypersensitivity reactions. Rare, serious post-injection reactions from accidental IV administration • Hepatotoxicity (monitor LFTs). Not recommended in hepatitis B • Limited data in hepatitis C, monitor LFTs • Opportunistic infections • Immune reactivation syndrome • QTc prolongation at supratherapeutic doses – caution with medicines associated with Torsade de Pointes • Not to be used with other antiretrovirals for HIV • Caution with narrow therapeutic index OAT1/3 substrates, e.g. methotrexate. If macrolide antibiotics required, consider azithromycin • Caution with oral treatments and H2 antagonists and antacids. • Limited data on the use of Vocabria in patients aged 65 years and over.
The following adverse events have been reported
Injection site reactions (generally mild/moderate) including cellulitis and abscess formation (uncommon), headache, pyrexia (mostly reported within one week of injection), depression, depressed mood, anxiety, abnormal dreams, insomnia/sleep disorder, somnolence, dizziness, dry mouth, decreased appetite, nausea, vomiting, abdominal pain/discomfort, flatulence, diarrhoea, fatigue, asthenia, malaise, rash, myalgia, weight increase, hepatotoxicity, pancreatitis, increased transaminases, increased bilirubin, decreases in white blood cells, haemoglobin and platelet count, increases in cholesterol, triglycerides, pancreatic amylase, and lipase Please refer to the full prescribing information for further information and prior to administration. Abbreviated Prescribing Information based on PI version: Vocabria 30mg film-coated tab- HK022021(GDS03/EU20210105); Vocabria 400mg, 600mg prolonged-release suspension for injection - version HK022021 (GDS03/EU20210105). For adverse events report, please call GlaxoSmithKline Limited at (852)3189 8989 or send an email to us at HKAdverseEvent@gsk.com.

Vocabria (cabotegravir 30mg film-coated tablets and 600mg prolonged-release suspension for injection in 3mL), and Rekambys (rilpivirine 900mg prolonged-release suspension for injection in 3mL).
Indication: Cabotegravir in combination with rilpivirine for treatment of HIV-1 in adults who are virologically suppressed (HIV-1 RNA <50 copies/mL) on a stable antiretroviral regimen without present or past evidence of viral resistance to, and no prior failure with agents of NNRTI and INI class. **Dosing:** *Adults (over 18 years)* carefully selected who agree to the injection schedule and are counselled about the importance of adherence. An oral lead in prior to the initiation of injections can be used to assess tolerability. For oral lead in: Prior to injections, once-daily oral dosing of cabotegravir 30mg tablet and rilpivirine 25mg tablet for approximately 1 month (at least 28 days) with food. Initiation injections following oral lead in: months 2 (final day of oral lead-in therapy) and 3. Separate intramuscular (gluteal) 3mL initiation injections of Vocabria and Rekambys. Continuation injections: Two months after the final initiation injections and every 2 months thereafter. Separate intramuscular (gluteal) 3mL injections of Vocabria and Rekambys. Injections may be administered up to 7 days before or after the due date. Please refer to the prescribing information for advice outside this window or missed injections. Caution in severe renal impairment or moderate hepatic impairment. Not recommended in severe hepatic impairment. **Contraindications:** Hypersensitivity to any ingredient. Coadministration with rifampicin, rifapentine, rifabutin, phenytoin, phenobarbital, carbamazepine, oxcarbazepine, systemic dexamethasone (except single dose), St John's Wort. **Special warnings/precautions:** If discontinued, adopt a fully suppressive antiretroviral regimen no later than when the next injection would have been due. If virologic failure is suspected an alternative regimen should be adopted as soon as possible. Residual concentrations may remain for prolonged periods after discontinuation. Increased risk of failure associated with 2 or more of: archived rilpivirine resistance mutations BMI ≥30 kg/m^2 or HIV-1 A6/A1 subtype. Caution if uncertain treatment history without pre-treatment resistance analyses, if BMI ≥30 kg/m^2, or HIV-1 A6/A1 subtype. Hypersensitivity reactions. Rare, serious post-injection reactions from accidental IV administration. Hepatotoxicity (monitor LFTs). Not recommended in hepatitis B. Limited data in hepatitis C monitor LFTs. Opportunistic infections. Immune reactivation syndrome. QTc prolongation at supratherapeutic doses – caution with medicines associated with Torsade de Pointes. Not to be used with other antiretrovirals for HIV. Caution with narrow therapeutic index OAT1/3 substrates, e.g. methotrexate. If macrolide antibiotics required, consider azithromycin. Caution with oral treatments and antacids. Please refer to the prescribing information for full list of interactions. **Pregnancy/breast feeding:** Not recommended. **Side effects:** Please refer to prescribing information for full details. Injection site reactions (generally mild/moderate) including cellulitis and abscess formation (uncommon), headache, pyrexia (mostly reported within one week of injection), depression, depressed mood, anxiety, abnormal dreams, insomnia/sleep disorder, somnolence, dizziness, dry mouth, decreased appetite, nausea, vomiting, abdominal pain/discomfort, flatulence, diarrhoea, fatigue, asthenia, malaise, rash, myalgia, weight increase, hepatotoxicity, pancreatitis, increased transaminases, increased bilirubin, decreases in white blood cells, haemoglobin and platelet count, increases in cholesterol, triglycerides, pancreatic amylase, and lipase **Please read the full prescribing information prior to administration.** Full prescribing information is available on request from GlaxoSmithKline Ltd, 23/F, Tower 6, The Gateway, 9 Canton Road, Tsimshatsui, Kowloon, Hong Kong. Abbreviated Prescribing Information based on PI version: Vocabria 30mg film-coated tab- HK022021(GDS03/EU20210105); Vocabria 600mg prolonged-release suspension for injection - version HK022021 (GDS03/EU20210105); Rekambys 900mg prolonged-release suspension for injection - EU SmPC 28 July 2021; (Hong Kong Approval Date: 16.Dec.2021). For adverse events report, please call GlaxoSmithKline Limited at (852)3189 8989 or send an email to us at HKAdverseEvent@gsk.com

VOCABRIA injection is indicated, in combination with REKAMBYS injection, for the treatment of HIV-1 infection in adults who are virologically suppressed (HIV-1 RNA <50 copies/mL) on a stable antiretroviral regimen without present or past evidence of viral resistance to, and no prior virological failure with agents of the NNRTI and INI class.[1]

HIV-1=human immunodeficiency virus type 1; **INI**=integrase inhibitor; **NNRTI**=non-nucleoside reverse transcriptase inhibitor.

References: 1. VOCABRIA Hong Kong Product Characteristics GDS03. **2.** REKAMBYS Summary of Product Characteristics. Janssen Healthcare; 2021. **3.** Overton ET, Richmond G, Rizzardini G, et al. Long-acting cabotegravir and rilpivirine dosed every 2 months in adults with HIV-1 infection (ATLAS-2M), 48-week results: a randomised, multicentre, open-label, phase 3b, non-inferiority study. Lancet. Published online ahead of print: Decem ber 9, 2020. doi: 10.1016/S0140-6736(20)32666-0.

Working together in HIV

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PM-HK-CBR-ADVT-220001
Date of Preparation: 13/02/2022 (02/24)