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The Hong Kong Society for Infectious Diseases
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24th Annual Scientific Meeting

Respiratory Infections

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Free of food restrictions*

Free of HIV boosters

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* Can be administrated with or without food

Efficacy regardless of baseline viral load[2]

Significantly fewer neuropsychiatric adverse events vs. comparator in three pre-specified categories[2,#]

Convenient dosing[1]

Dizziness, Sleep disorders/disturbances and Altered sensorium

Study Design[2]
DRIVE-AHEAD is a phase 3, randomized, non-inferiority trial. Antiretroviral treatment–naive adults were randomized (1:1) to once-daily, fixed-dose DOR at 100 mg, lamivudine at 300 mg, and tenofovir disoproxil fumarate (TDF) at 300 mg (DOR/3TC/TDF) or to efavirenz at 600 mg, emtricitabine at 200 mg, and TDF at 300 mg (EFV/FTC/TDF) for 96 weeks. The primary efficacy endpoint was the proportion of participants with <50 HIV-1 RNA copies/mL at week

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.**

References: 1. Delstrigo HKPC. **2.** Orkin C, Squires KE, Molina JM, *et al*; and DRIVE-AHEAD Study Group. Doravirine/lamivudine/tenofovir disoproxil fumarate is non-inferior to efavirenz/emtricitabine/tenofovir disoproxil fumarate in treatment-naive adults with human immunodeficiency virus-1 infection: week 48 results of the DRIVE-AHEAD trial. *Clin Infect Dis*. 2019;68(4):535-544.

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

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MAT-HK-2000099-1.0-06/2020

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.

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.***
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SANOFI PASTEUR

24th Annual Scientific Meeting

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24th Annual Scientific Meeting

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-fourth and the first ever virtual Annual Scientific Meeting (ASM).

For the past two decades, our ASMs have been providing an excellent platform for healthcare professionals in Hong Kong to interchange latest update and cutting edge-advancement in the field, from scientific development to clinical practice to public health issues. Amidst the COVID-19 pandemic, we are facing various kinds of challenges. To cope with the "new normal", this year, we stage this prime event of our Society to an on-line virtual platform. We believe the event will be as interactive as previous years and our participants will find the novel on-line experience equally enjoyable.

The main theme of ASM this year is on respiratory infections. We are honoured to have Professor Frederick Hayden from USA to share with us the latest new advances on antivirals for influenza. As for the local experiences, we are privileged to have Professor Ivan Hung to discuss vaccine preventable respiratory infection, and Dr. Kwok-chiu Chang to share his experiences in the diagnosis of latent tuberculosis. To engage participation of local experts, there will be a case sharing session for discussion on management of COVID-19 in Hong Kong.

I would like to take this precious opportunity to express my heartfelt appreciation to our co-organizer Hong Kong Thoracic Society, 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 Wai-chi Lin
President
The Hong Kong Society for Infectious Diseases

The Council

The Hong Kong Society for Infectious Diseases
(April 2020 – March 2022)

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Dr. Joseph Kay-yan Tsang
Dr. Bonnie Chun-kwan Wong
Dr. Alan Ka-lun Wu
Dr. JonPaul Sze-tsing Zee

24th Annual Scientific Meeting

Programme

13:10 - 13:30	**Annual General Meeting**
13:35 - 13:40	**Welcome Speech** Dr. Ada Wai-chi Lin, President, The Hong Kong Society for Infectious Diseases
13:40 - 14:40	**Case Sharing on Management of COVID-19** Chairpersons: Dr. Ada Wai-chi Lin and Dr. Andrew Tin-yau Wong **Sharing of COVID-19 Cases in Hong Kong** Dr. Jacky Man-chun Chan Associate Consultant, Department of Medicine and Geriatrics Princess Margaret Hospital, Hong Kong **Immunomodulating Treatment of COVID-19** Dr. Helen Shuk-ying Chan Associate Consultant, Infectious Diseases Team, Department of Medicine Queen Elizabeth Hospital, Hong Kong **Q & A**
14:40 - 15:15	**Symposium I** Chairpersons: Dr. Wilson Lam and Dr. JonPaul Sze-tsing Zee **Vaccine Preventable Respiratory Infection and Beyond** Professor Ivan Fan-ngai Hung Chief, Division of Infectious Diseases, Department of Medicine The University of Hong Kong, Queen Mary Hospital, Hong Kong **Q & A**
15:15 - 15:30	**Break**
15:30 - 16:00	**Symposium II** Chairpersons: Dr. Sin-man Lam and Dr. Bonnie Chun-kwan Wong **Diagnosis of Latent Tuberculosis Infection** Dr. Kwok-chiu Chang Senior Medical Officer, Tuberculosis and Chest Service Department of Health, Hong Kong **Q & A**
16:00 - 16:35	**Symposium III** Chairpersons: Dr. Jacky Man-chun Chan and Dr. Alan Ka-lun Wu **Update on Antivirals for Influenza** Professor Frederick Hayden Professor Emeritus of Medicine and Stuart S. Richardson Professor Emeritus of Clinical Virology University of Virginia School of Medicine, Charlottesville, USA **Q & A**
16:35 - 16:40	**Closing Speech** Dr. Wilson Lam, Vice-President, The Hong Kong Society for Infectious Diseases

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Organization	Points Accredited
Hong Kong College of Community Medicine	3
Hong Kong College of Emergency Medicine (Cat B)	3
The Hong Kong College of Family Physicians (Cat 5.2)	3
The Hong Kong College of Obstetricians and Gynaecologists	3
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Continuing Nursing Education (Accredited by Hong Kong Thoracic Society)	2.5

24th Annual Scientific Meeting

Faculty

The Council of the Society would like to thank the faculty members for their invaluable contributions to the 24th Annual Scientific Meeting.

Dr. Jacky Man-chun Chan

Associate Consultant, Department of Medicine and Geriatrics, Princess Margaret Hospital, Hong Kong

Dr. Helen Shuk-ying Chan

Associate Consultant, Infectious Diseases Team, Department of Medicine, Queen Elizabeth Hospital, Hong Kong

Dr. Kwok-chiu Chang

Senior Medical Officer, Tuberculosis and Chest Service, Department of Health, Hong Kong

Professor Frederick Hayden

Professor Emeritus of Medicine and Stuart S. Richardson Professor Emeritus of Clinical Virology, University of Virginia School of Medicine, Charlottesville, USA

Professor Ivan Fan-ngai Hung

Chief, Division of Infectious Diseases, Department of Medicine, The University of Hong Kong, Hong Kong

Dr. Sin-man Lam

Associate Consultant, Intensive Care Unit (ICU), Pamela Youde Nethersole Eastern Hospital, Hong Kong

Dr. Wilson Lam

Specialist in Infections Disease, Private Practice, Hong Kong

Dr. Ada Wai-chi Lin

Principal Medical & Health Officer, Emergency Response and Programme Management, Centre for Health Protection, Department of Health, Hong Kong

Dr. Andrew Tin-yau Wong

Honorary Consultant, Infectious Disease Centre & Department of Medicine and Geriatrics, Princess Margaret Hospital, Hong Kong

Dr. Bonnie Chun-kwan Wong

Senior Medical & Health Officer, Special Preventive Programme, Centre for Health Protection, Department of Health, Hong Kong

Dr. Alan Ka-lun Wu

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Hospital Infection Control Officer, Ruttonjee & Tang Shiu Kin Hospitals, Hong Kong

Dr. JonPaul Sze-tsing Zee

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

Case Sharing on Management of COVID-19

Sharing of COVID-19 Cases in Hong Kong

Dr. Jacky Man-chun Chan

Associate Consultant, Department of Medicine and Geriatrics, Princess Margaret Hospital, Hong Kong

In this session, we will have a general review of COVID-19 infections including clinical presentations, biochemical and radiological manifestations. Several cases will be presented to illustrate the typical and atypical presentations and the clinical course of mild to severe cases. For most cases, general supportive treatments including symptomatic medications and regular clinical monitoring are provided. For some cases, the use of interferon-based treatment was implemented including subcutaneous interferon beta-1b injection, oral ribavirin and lopinavir-ritonavir. Intravenous remdesivir was also used in some moderate to severe cases. For moderate to severe cases, adjuvant use of subcutaneous heparin for venous thrombosis prophylaxis and corticosteroids were also implemented. We will focus on the different clinical presentations and treatment modalities in this session.

Case Sharing on Management of COVID-19

Immunomodulating Treatment of COVID-19

Dr. Helen Shuk-ying Chan

Associate Consultant, Infectious Diseases Team, Department of Medicine, Queen Elizabeth Hospital, Hong Kong

Coronavirus Disease 2019 (COVID-19) manifests with a wide clinical spectrum, ranging from asymptomatic to severe viral pneumonia and acute respiratory distress syndrome (ARDS). Severe COVID-19 is marked by a dysregulated immune response with moderate to severe systemic inflammation and/or immunoparalysis. Thus, immunomodulation is considered as one of the current mainstays of treatment in severe COVID-19. Moderate dose of corticosteroid (dexamethasone 6mg daily for 10 days) was showed to be effective to lower 1/5 of mortality in patients required supplemental oxygen and 1/3 of deaths in patients on mechanical ventilation. However, the benefits of using other immune-modulators in patients with severe COVID-19 were conflicting. Tocilizumab, a humanized anti–interleukin-6 receptor monoclonal antibody, had demonstrated inconsistent results in terms of reduction of disease progression and survival benefits in severe COVID-19 in several randomized control trials. Faster recovery and clinical outcome was observed in hospitalized adults with COVID-19 treated with baricitinib (a Janus kinase inhibitor) and remdesivir compared with remdesivir monotherapy.

Symposium I

Vaccine Preventable Respiratory Infection and Beyond

Professor Ivan Fan-ngai Hung

Chief, Division of Infectious Diseases, Department of Medicine, The University of Hong Kong, Hong Kong

With the decline in birth rate and the increase in life expectancy, the proportion of adults and older adults in our society is increasing rapidly. In Hong Kong, those aged 20 and above account for 84.8% of the population, and those aged above 50 account for 42.2% of the whole population.

The immune system of adults gradually weakens with age through immunosenescence. As a result, older individuals are more susceptible to vaccine-preventable infectious diseases, including respiratory infections such as pneumococcal disease and influenza, which have relatively high awareness in the society with government vaccination programmes in place; pertussis, a forgotten but resurging disease that has high infant mortality rate but with the burden shifting to adults and older adults in recent years; shingles, a disease that has age-related decline in immunity as the dominant driver; as well as other diseases including tetanus and hepatitis B.

This presentation will summarize the diseases, epidemiology, and burden of the vaccine preventable respiratory infections, as well as other infections that pose an increasing risk for infections and complications in adults and older adults and continue to be a significant burden to the society and the healthcare system.

Vaccination recommendations and programmes that minimise the universal incidence and burden, as well as recent recommendations on vaccination strategies from WHO, US CDC and other European countries amid the current COVID pandemic will also be discussed.

Symposium II

Diagnosis of Latent Tuberculosis Infection

Dr. Kwok-chiu Chang

Senior Medical Officer, Tuberculosis and Chest Service, Department of Health, Hong Kong

Latent infection with Mycobacterium tuberculosis, often called latent tuberculosis infection (LTBI), is pragmatically defined as presumptive infection with M. tuberculosis inferred by TB immunoreactivity using immunodiagnostic tests, which is either a tuberculin skin test (TST) or an interferon-gamma release assay (IGRA), in the absence of any clinical or radiological signs of active TB. As many TB cases occur due to endogenous reactivation of LTBI, the diagnosis and treatment of LTBI may contribute towards ending the global TB epidemic.

LTBI ranges from incipient and subclinical infection to elimination of infection. Characterized by a high short-term likelihood of progression to active TB, incipient TB has been defined by the World Health Organization (WHO) as the prolonged asymptomatic phase of early disease before clinical presentation as active TB. Both TST and IGRA have modest positive predictive values (PPV) for incident TB owing to a low pre-test probability of incident TB, and suboptimal diagnostic accuracy for incipient TB.

In search for better biomarkers for incident TB, WHO has introduced a target product profile for incipient TB diagnostics, which stipulates 75% sensitivity and specificity as minimum, and 90% as optimal, over a two-year period. A systematic review identified eight mRNA signatures with equivalent diagnostic accuracy for incipient TB over a two-year period. Based on a 2% pre-test probability, their PPV were 6.8-9.4% over 24 months and 11.2-14.4% over 3 months. Yet none met the minimum WHO target profile.

It is probably necessary to continue to optimise targeted use of current LTBI diagnostics among high-risk subjects.

Symposium III

Update on Antivirals for Influenza

Professor Frederick Hayden

Professor Emeritus of Medicine and Stuart S. Richardson Professor Emeritus of Clinical Virology, University of Virginia School of Medicine, Charlottesville, USA

Recent influenza antiviral developments include approvals of intravenous zanamivir (EMA) and oral baloxavir. Although intravenous zanamivir was comparable to oral oseltamivir in hospitalized patients, zanamivir's spectrum includes many oseltamivir-resistant variants. RCTs testing antibody-based therapeutics have yielded largely disappointing results. Three oral inhibitors (favipiravir, pimodivir, baloxavir) targeting the influenza polymerase complex (PB1, PB2, and PA endonuclease, respectively) have shown antiviral efficacy in uncomplicated influenza and enhanced antiviral effects when combined with NAIs. However, clinical development of pimodivir has stopped recently because, when combined with standard-of-care (SOC), it did not show greater clinical effects than SOC alone in hospitalized influenza A patients. Favipiravir, approved in Japan in 2014 with very restricted indications (potential teratogenicity), has shown some clinical efficacy in uncomplicated influenza; an observational study found that the combination of favipiravir and oseltamivir was superior to oseltamivir alone in severely ill patients. Single-dose baloxavir significantly shortens illness in otherwise healthy adults and children and higher-risk outpatients compared to placebo and is effective for post-exposure prophylaxis. Its clinical efficacy is similar to oseltamivir in influenza A but is superior in influenza B. Baloxavir shows greater antiviral efficacy than oseltamivir, but variants with PA substitutions at position I38 conferring reduced susceptibility sometimes emerge during treatment and appear transmissible. In hospitalized patients a placebo-controlled RCT of baloxavir-NAI combination therapy found greater antiviral effects but no better clinical outcomes than NAI monotherapy. RCTs to determine whether antiviral treatment reduces influenza transmission to contacts and which immunomodulatory interventions combined with antivirals benefit those hospitalized with serious illness are in progress.

24th Annual Scientific Meeting

Acknowledgements

The Council of the Society would like to extend their heartfelt thanks to the sponsors for their generous support to the 24th Annual Scientific Meeting.

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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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‡0 cases of treatment-emergent resistance in registrational trials at week 144.[3]
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3TC, lamivudine; ABC, abacavir; AEs, adverse events; CI, confidence interval; DTG, dolutegravir; FTC, emtricitabine; 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.** Tsiang M, Jones GS, Goldsmith J, et al. Antiviral activity of bictegravir (GS-9883), a novel potent HIV-1 integrase strand transfer inhibitor with an improved resistance profile. Antimicrob Agents Chemother. 2016;60(12):7086-97. **3.** Orkin C, DeJesus E, Sax PE, et al. Fixed-dose combination bictegravir, emtricitabine, and tenofovir alafenamide versus dolutegravir-containing regimens for initial treatment of HIV-1 infection: week 144 results from two randomised, double-blind, multicentre, phase 3, non-inferiority trials. Lancet HIV 2020; 7(6): e389-e400.

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).
HKBIK0095_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

Veklury®
remdesivir

VEKLURY® IS THE FIRST ANTIVIRAL TREATMENT
approved for SARS-CoV-2 infection[1]

PRECAUTIONS RELATING TO INDICATION[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.
- In line with the majority of use in clinical trials to date, 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.

The image is shown for illustration purpose only, it does not represent the actual appearance of the product.
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.

ECMO=extracorporeal membrane oxygenation. SARS-CoV-2=severe acute respiratory syndrome coronavirus 2.

Reference: 1. VEKLURY Hong Kong Prescribing Information (version: 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/1.73m2 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.** Veklury is a registered trademark of Gilead Sciences, Inc., or its related companies.

Hong Kong: For medical enquiries, please send your request to asiamedinfo@gilead.com or call 800 908 348 (toll-free number)
Macau: For medical enquiries, please send your request to asiamedinfo@gilead.com or call 0800827 (toll-free number)

HKVEK0001_v1.0 11/19/2020

GILEAD
Creating Possible

Room 2603, 26th Floor, Hysan Place,
500 Hennessy Road, Causeway Bay, Hong Kong
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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 aminotransferase (ALT) and/or aspartate aminotransferase (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: 30/01/2020 (01/2021)

In the management of HIV,

TIMES ARE CHANGING

Are your treatment decisions changing with them?
Now is the time

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-190007
Date of preparation: 30/09/2019

SHINGRIX
(ZOSTER VACCINE
RECOMBINANT, ADJUVANTED)

Available soon

Even a healthy patient ≥ 50 years old is at risk for **shingles**.[1-5]

The ONLY shingles vaccine to provide >90% efficacy against shingles in all age groups ≥50 years old.[6,8]

SHINGRIX is recommended by the CDC as the **preferred vaccine** for the prevention of shingles[7]:

☑ **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.

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'-monophosphoryl lipid 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. Mahalingam R, Wellish M, Wolf W, Dueland AN, Cohrs R, Vafai A, et al. Latent varicella-zoster viral DNA in human trigeminal and thoracic ganglia. N Engl J Med. 1990 Sep;323(10):627-31. **2.** Lungu O, Annunziato PW, Gershon A, Staugaitis SM, Josefson D, LaRussa P, et al. Reactivated and latent varicella-zoster virus in human dorsal root ganglia. Proc Natl Acad Sci U S A. 1995 Nov;92(24):10980-84. **3.** Furuta Y, Takasu T, Fukuda S, Sato-Matsumura KC, Inuyama Y, Hondo R, et al. Detection of varicella-zoster virus DNA in human geniculate ganglia by polymerase chain reaction. J Infect Dis. 1992 Nov;166(5):1157-59. **4.** Weinberg A, Lazar AA, Zerbe GO, Hayward AR, Chan IS, Vessey R, et al. Influence of age and nature of primary infection on varicella-zoster virus--specific cell-mediated immune responses. J Infect Dis. 2010;201(7):1024-30. **5.** Centers for Disease Control and Prevention. Prevention of herpes zoster: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR. 2008 May;57(RR-5):1-30. **6.** GSK. SHINGRIX Hong Kong full prescribing information GDS03. **7.** Centers for Disease Control and Prevention. Recommendations of the Advisory Committee on Immunization Practices for Use of Herpes Zoster Vaccines. MMRW. 2018,67(3);103–108. **8.** MSD. Zoster live, attenuated vaccine Product Circular.

PM-HK-SGX-JRNA-210001 (01/2023) Date of preparation: 17/02/2021

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

gsk

THE FIRST PI-BASED STR BUILT ON THE NEWEST BACKBONE IN ARV THERAPY

Your Resilience Matters

Help protect against resistance with the barrier to rely on from the start

Symtuza®
darunavir/cobicistat/emtricitabine/tenofovir alafenamide tablets
800mg/150mg/200mg/10mg

The Only Evidence-Based STR Proven in Rapid Initiation

SYMTUZA® is the only STR that delivers these combined benefits:

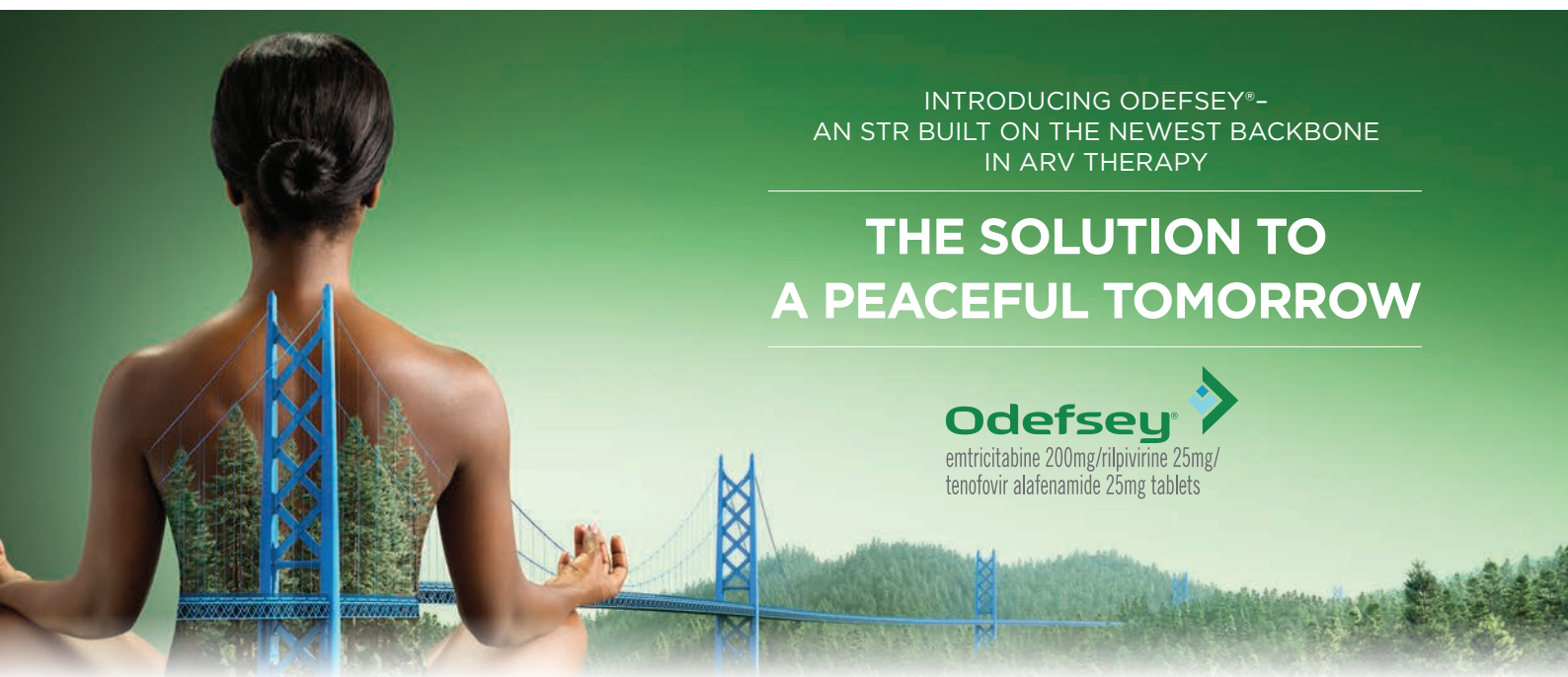
- **High Genetic Barrier of Darunavir***
- **Complete Coverage of HIV Patients†**
- **Formulated for Improved Tolerability‡**

* Zero treatment-emergent darunavir, primary PI, or TAF mutations across clinical trial populations. In the AMBER trial, of 362 treatment-naïve patients taking SYMTUZA®, 8 met the criteria for VF and 7 patients experiencing VF were analyzed for resistance[1]. In the EMERALD trial, of 763 virologically suppressed patients taking SYMTUZA®, 6 met the criteria for VF and 1 patient experiencing VF was analyzed for resistance[2]. Only 1 patient receiving SYMTUZA® was found to have M184I/V; this patient also had a transmitted K103N mutation at screening[1].

† Efficacy demonstrated in treatment-naïve and virologically suppressed patients, and in a rapid initiation scenario[1-3].

‡ ≤2% discontinuation rates due to adverse events through 48 weeks.[1,2]

INDICATION
SYMTUZA® is indicated for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults (aged 18 years and older)[4].



INTRODUCING ODEFSEY®–
AN STR BUILT ON THE NEWEST BACKBONE IN ARV THERAPY

THE SOLUTION TO A PEACEFUL TOMORROW

Odefsey®
emtricitabine 200mg/rilpivirine 25mg/tenofovir alafenamide 25mg tablets

INDICATION
ODEFSEY® is indicated for the treatment of adults and adolescents (aged 12 years and older with body weight at least 35 kg) infected with human immunodeficiency virus-1 (HIV-1) without known mutations associated with resistance to the non-nucleoside reverse transcriptase inhibitor (NNRTI) class, tenofovir or emtricitabine and with a viral load ≤ 100,000 HIV-1 RNA copies/mL[5].

ARV=antiretroviral; HIV=human immunodeficiency virus; PI=protease inhibitor; STR=single-tablet regimen; TAF=tenofovir alafenamide; VF=virologic failure.

References: 1. Eron JJ, Orkin C, Gallant J, et al. A week-48 randomized phase-3 trial of darunavir/cobicistat/emtricitabine/tenofovir alafenamide in treatment-naive HIV-1 patients. AIDS. 2018;32(11):1431-42. **2.** Orkin C, Molina J-M, Negredo E, et al. Efficacy and safety of switching from boosted protease inhibitors plus emtricitabine and tenofovir disoproxil fumarate regimens to single-tablet darunavir, cobicistat, emtricitabine, and tenofovir alafenamide at 48 weeks in adults with virologically suppressed HIV-1 (EMERALD): a phase 3, randomised, non-inferiority trial. Lancet HIV. 2018;5(1):e23-e34. **3.** Department of Health and Human Services. Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents 2019 [cited 2020 Jun 03]. Available from: https://aidsinfo.nih.gov/ contentfiles/lvguidelines/adultandadolescentgl.pdf. **4.** SYMTUZA® Hong Kong Prescribing Information. **5.** ODEFSEY® Hong Kong Prescribing Information.

Symtuza® Tablets
ABBREVIATED PRESCRIBING INFORMATION
ACTIVE INGREDIENT(S): Darunavir 800mg/ cobicistat 150mg/ emtricitabine 200mg/ tenofovir alafenamide 10mg INDICATION(S): Treatment of HIV-1 infection in adults (aged 18 years and older). Genotypic testing should guide the use of Symtuza. DOSAGE & ADMINISTRATION: One tablet once daily with food. Tablet should not be crushed. May be used in patients with prior exposure to antiretroviral medicinal products but without darunavir resistance associated mutations (DRV-RAMs) and who have plasma HIV-1 RNA < 100,000 copies/mL and CD4+ cell count 100 cells x 106/L. Use with caution in patients above 65 years of age and patients with mild or moderate hepatic impairment. Discontinue use in patients with eGFRCG that declines below 30 mL/min during treatment. CONTRAINDICATIONS: Patients with severe hepatic impairment. Patients with eGFRCG < 30 mL/min. Treatment-experienced patients with one or more DRV-RAMs or with HIV-1 RNA ≥ 100,000 copies/mL or CD4+ cell count < 100 cells x 106/L. Hypersensitivity to the active substances or to any of the excipients. Carbamazepine, phenobarbital, phenytoin, rifampicin, lopinavir/ritonavir, St. John's wort (Hypericum perforatum), alfuzosin, amiodarone, dronedarone, quinidine, ranolazine, colchicine when used in patients with renal and/or hepatic impairment, rifampicin, ergot derivatives, pimozide, quetiapine, sertindole, lurasidone, triazolam, midazolam administered orally, sildenafil (when used for treatment of pulmonary arterial hypertension, avanafil, simvastatin, lovastatin and lomitapide), dabigatran, ticagrelor, tenofovir disoproxil (as fumarate, phosphate or succinate), lamivudine, adefovir dipivoxil (when used for treatment of HBV infection). Other antiretroviral products. Medicinal products requiring pharmacokinetic enhancement with ritonavir or cobicistat. SPECIAL WARNINGS & PRECAUTIONS: Patients co-infected with HIV and HBV or HCV: Patients with chronic hepatitis B or C treated with antiretroviral therapy are at increased risk for potentially fatal hepatic adverse reactions. Discontinuation in patients co-infected with HIV and HBV may be associated with severe acute exacerbations of hepatitis. Closely monitor these patients with both clinical and laboratory follow-up for at least several months. Do not recommend discontinuation in patients with advanced liver disease or cirrhosis. Mitochondrial dysfunction: Any child exposed in utero to nucleoside and nucleotide analogues, even HIV negative children, should have clinical and laboratory follow-up and should be fully investigated for possible mitochondrial dysfunction in case of relevant signs or symptoms. Hepatotoxicity: Patients with pre-existing liver dysfunction have increased risk for potentially fatal hepatic adverse reactions. Conduct appropriate laboratory testing prior to initiating Symtuza and monitor patients during treatment. Consider increased AST/ALT monitoring in patients with underlying chronic hepatitis, cirrhosis, or who have pre-treatment elevations of transaminases. Consider discontinuing Symtuza if there is evidence of new or worsening liver dysfunction. Nephrotoxicity: Potential risk of nephrotoxicity cannot be excluded. Renal impairment: Cobicistat has been shown to decrease estimated creatinine clearance. Take this into consideration when Symtuza is used in patients, in whom the estimated creatinine clearance is used to guide aspects of their clinical management. Patients with co-existing conditions: Haemophiliac patients should be made aware of the possibility of increased bleeding. Severe skin reactions: Discontinue Symtuza immediately if signs or symptoms of severe skin reactions develop. Sulphonamide allergy: Use with caution in patients with a known sulphonamide allergy. Weight and metabolic parameters: For monitoring of blood lipids and glucose reference is made to established HIV treatment guidelines. Osteonecrosis: Advise patients to seek medical advice if they experience joint aches and pain, joint stiffness or difficulty in movement. Immune Reactivation Syndrome: Any inflammatory symptoms should be evaluated and treatment instituted when necessary. Opportunistic infections: Patients receiving Symtuza should remain under close clinical observation by physicians. SIDE EFFECTS: Diarrhoea, rash, headache, nausea, fatigue, abdominal pain. Refer to the full prescribing information for other side effects. PREGNANCY & LACTATION: Treatment with darunavir/cobicistat during pregnancy results in low darunavir exposure, which may be associated with an increased risk of treatment failure and an increased risk of HIV transmission to the child. Do not initiate Symtuza during pregnancy, and women who become pregnant during therapy with Symtuza should be switched to an alternative regimen. Mothers should be instructed not to breast-feed if they are receiving Symtuza. INTERACTIONS: Substrates of transporters p-glycoprotein (P-gp), BCRP, MATE1, OATP1B1 and OATP1B3. Medicinal products primarily metabolised by CYP3A. CYP3A inducers and inhibitors. Medicinal products that are eliminated by active tubular secretion. Medicinal products that decrease renal function, or strongly affect P-gp activity and BCRP, or induce P-gp activity, or inhibit P-gp. PLEASE REFER TO FULL PRESCRIBING INFORMATION BEFORE PRESCRIBING. Symtuza aPI ver 2.0

Odefsey® Tablets
ABBREVIATED PRESCRIBING INFORMATION
ACTIVE INGREDIENT(S): Emtricitabine 200mg/ rilpivirine 25mg/ tenofovir alafenamide 25mg INDICATION(S): Treatment of adults and adolescents (aged ≥12 years with body weight ≥35 kg) infected with HIV-1 without known mutations associated with resistance to the non-nucleoside reverse transcriptase inhibitor (NNRTI) class, tenofovir or emtricitabine and with a viral load ≤ 100,000 HIV-1 RNA copies/mL. DOSAGE & ADMINISTRATION: One tablet once daily with food. Do not initiate Odefsey in patients with estimated CrCl < 30 mL/min. Discontinue Odefsey in patients with estimated CrCl that declines < 30 mL/min during treatment. Odefsey should be used with caution in patients with moderate hepatic impairment. Odefsey is not recommended for use in patients with severe hepatic impairment. CONTRAINDICATIONS: Hypersensitivity to the active substances or to any of the excipients. Other antiretroviral medicinal products. Other medicinal products containing tenofovir alafenamide, lamivudine, tenofovir disoproxil or adefovir dipivoxil. Medicinal products that can result in significant decreases in rilpivirine plasma concentrations (due to cytochrome P450 [CYP]3A enzyme induction or gastric pH increase), which may result in loss of therapeutic effect of Odefsey, including: carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifabutin, rifampicin, rifapentine, omeprazole, esomeprazole, dexlansoprazole, lansoprazole, pantoprazole, rabeprazole, dexamethasone (oral and parenteral doses), except as a single dose treatment. St. John's wort (Hypericum perforatum). SPECIAL WARNINGS & PRECAUTIONS: Virologic failure and development of resistance: Insufficient data to justify use in patients with prior NNRTI failure. Resistance testing and/or historical resistance data should guide the use of Odefsey. Cardiovascular: Odefsey should be used with caution when co-administered with medicinal products with a known risk of Torsade de Pointes. 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. Patients co-infected with HIV and HBV who discontinue Odefsey 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. 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. Opportunistic infections: Patients receiving Odefsey may continue to develop opportunistic infections and other complications of HIV infection, and therefore should remain under close clinical observation by physicians experienced in the treatment of patients with HIV associated diseases. Osteonecrosis: Cases of osteonecrosis have been reported particularly in patients with advanced HIV disease and/or long-term exposure to CART. Advise patients to seek medical advice if experience joint aches and pain, joint stiffness or difficulty in movement. Excipients: Odefsey contains lactose monohydrate. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency, or glucose-galactose malabsorption should not take Odefsey. SIDE EFFECTS: Nausea, diarrhea, headache, dizziness, abnormal dreams, insomnia. Refer to the full prescribing information for other side effects. PREGNANCY & LACTATION: It is preferable to avoid the use of Odefsey during pregnancy. It is recommended that HIV infected women do not breast-feed their infants under any circumstances. INTERACTIONS: CYP enzyme inhibitors. QT prolonging medicinal products. PLEASE REFER TO FULL PRESCRIBING INFORMATION BEFORE PRESCRIBING. Odefsey aPI ver 1.0

CP-180420 Feb 2021 4IC_1348

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janssen Infectious Diseases
PHARMACEUTICAL COMPANIES OF Johnson & Johnson

VaxigripTetra®

Quadrivalent influenza vaccine
(split virion, inactivated)

Your trusted partner in influenza protection for your patients

Presentation: Quadrivalent influenza vaccine (inactivated, split virion), suspension for injection in pre-filled syringe. **Indications:** For the prevention of influenza disease caused by the two influenza A virus subtypes and the two influenza B virus types contained in the vaccine. Active immunization of adults, including pregnant women, and children from 6 months of age and older. Passive protection of infant(s) from birth to < 6 months of age following vaccination of pregnant women. **Posology:** Adults & children from 6 months to 17 years of age: one 0.5ml dose. Children < 9 years of age who have not been previously vaccinated: a second dose of 0.5ml should be given after an interval of at least 4 weeks. Passive protection: one 0.5ml dose given to pregnant women may protect infants from birth to < 6 months of age; however, not all these infants will be protected. **Contraindications:** Hypersensitivity to the active substances or to any of the excipients or to any component that may be present as traces such as eggs (ovalbumin, chicken proteins), neomycin, formaldehyde and octoxinol-9. Vaccination should be postponed in case of moderate or severe febrile disease or acute disease. **Precautions:** No administration via intravascular route. Anaphylactic reaction, subjects with thrombocytopenia or a bleeding disorder, fainting and syncopal reactions. Interactions: Separate injection sites and separate needles should be used in case of concomitant administration with other vaccines. The immunological response may be reduced in subjects undergoing immunosuppressant treatment. **Undesirable effects:** The most frequently reported adverse reaction after vaccination, in all populations was injection site pain. In subpopulation of children less than 24 months of age, irritability was the most frequently reported adverse reaction. In subpopulation children from 24 to 35 months of age, malaise is the most frequently reported adverse reaction. Very common and common adverse reactions include headache, myalgia, malaise, shivering, fever, injection site erythema, injection site swelling, injection site induration, injection site ecchymosis, injection site pain/tenderness, vomiting, lost appetite, abnormal crying, drowsiness. For uncommon, rare and very rare undesirable effects, please refer to the full prescribing information. **Preparations:** 0.5ml prefilled syringes x 1's or 10's. **Legal Classification:** Part 1, First & Third Schedules Poison. ***Full prescribing information is available upon request.***

API-HK-VXT-20.06

1. Vaxigriptetra package insert

MAT-HK-2000252-1.0-01/2021

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