The FIRST and ONLY inhibitor Specifically Targeting the ABL1 Myristoyl Pocket (STAMP) is now registered in Hong Kong. [1-3]

TREAT CML DIFFERENTLY WITH SCEMBLIX.

SCEMBLIX is the first treatment to demonstrate superior efficacy and a favorable tolerability profile vs a 2nd-generation TKI (bosutinib*) in a Phase 3 trial[1-2, 4-10^]

2x higher

SCEMBLIX doubled the MMR rate at Week 96 vs bosutinib* (37.6% vs 15.8%)[11]

SCEMBLIX

Nearly 4x lower

Discontinuation rate due to AEs was nearly 4 times lower with **SCEMBLIX** vs bosutinib* (7% vs 25%)[11]

SCEMBLIX had superior efficacy and a tolerable safety profile in a population resisiant and/or intolerant to prior TKIs[11]

- The most common adverse drug reactions of any grade (incidence ≥20%) in patients receiving SCEMBLIX at week 96 analysis were thrombocytopenia (36%)[a], Headache (31%) and neutropenia (30%)[b,11]

*Bosutinib is not yet registered in HK

^Ph+ CML-CP patients previously treated with 2 or more tyrosine kinase inhibitors. There is no head-to-head clinical trials comparison versus dasatinib or nilotinib.

Results from a study of 233 adults with Ph+ CML-CP, previously treated with ≥ 2 TKIs: 157 patients received SCEMBLIX at 40mg bid and 76 patients received bosutinib* at 500mg qd until unacceptable toxicity or treatment failure occurred.[11]

Abbreviation: AE, Adverse Event; bid, twice daily; CM, Chronic Myeloid Leukaemia; CP, Chronic Phase; MMR, Major molecular Response; Ph+, Philadelphia chromosome-positive; qd, once daily; TKI, Tyrosine Kinase Inhibitor.

SCEMBLIX abbreviated prescribing information

Important note: Before prescribing, consult full prescribing information. **Presentation:** Film-coated tablets containing 21.62 mg and 43.24 mg of asciminib hydrochloride, equivalent to 20 mg and 40 mg of asciminib. **Indications:** Scemblix is indicated for the treatment of adult patients with Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase (Ph+ CML-CP), previously treated with two or more tyrosine kinase inhibitors. **Dosage and administration:** The recommended dose is 40 mg twice daily without food at approximately 12-hour intervals. For complete dosage instructions, refer to the full prescribing information. **Special populations:** ♦**Renal impairment:** No dose adjustment in patients with mild to severe renal impairment. ♦**Hepatic impairment:** No dose adjustment in patients with mild to severe hepatic impairment. ♦**Pediatric patients (below 18 years):** Safety and efficacy not established. ♦**Elderly (65 years of age or above):** No dose adjustment. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. **Warnings and precautions:** ♦**Myelosuppression:** Complete blood counts should be performed every 2 weeks for first 3 months and monthly thereafter. Patients should be monitored for signs and symptoms. Dose reduction, temporarily withholding or permanent discontinuation should be based on severity of thrombocytopenia and/or neutropenia. ♦**Pancreatic toxicity:** Serum lipase and amylase should be assessed monthly and patients monitored for signs and symptoms. More frequent monitoring in patients with a history of pancreatitis recommended. If enzymes elevation accompanied by abdominal symptoms, temporarily withholding treatment and diagnostic tests to exclude pancreatitis recommended. Dose reduction, temporarily withholding or permanent discontinuation should be based on severity of serum lipase and amylase elevation. ♦**QT prolongation:** Electrocardiogram should be performed prior to the start of treatment and monitored during treatment. Correction of hypokalaemia and hypomagnesaemia prior to and monitored during treatment recommended. Caution recommended when administering concomitantly with medicinal products with known risk of torsades de pointes. ♦**Hypertension:** Hypertension, including severe hypertension, occurred in patients receiving asciminib. Hypertension and other cardiovascular risk factors should be monitored regularly. Management of hypertension with the standard therapies during asciminib treatment recommended. ♦**Hepatitis B (HBV) reactivation:** HBV reactivation occurred in chronic carriers following administration of other BCR:ABL1 tyrosine kinase inhibitors (TKIs). Testing for HBV infection prior to the start of treatment recommended. HBV carriers should be closely monitored for signs and symptoms of active HBV infection throughout therapy and for several months following termination of therapy. **Pregnancy, lactation, women of childbearing potential: Women of childbearing potential/Contraception:** Pregnancy status verification prior to the starting treatment with asciminib in women of childbearing potential. Sexually-active women of childbearing potential should use effective contraception (methods that result in less than 1% pregnancy rates) during treatment with asciminib and for at least 3 days after stopping treatment. **Pregnancy:** Asciminib is not recommended during pregnancy and in women of childbearing potential not using contraception. The patient should be advised of a potential risk to the foetus if asciminib is used during pregnancy or if the patient becomes pregnant while taking asciminib. **Breast-feeding:** Breast-feeding should be discontinued during treatment and for at least 3 days after stopping treatment with asciminib. **Fertility:** No data available on human fertility. **Adverse drug reactions: Very common (≥10%):** Upper respiratory tract infection, thrombocytopenia, neutropenia, anaemia, dyslipidaemia, headache, dizziness, hypertension, cough, pancreatic enzymes increased, vomiting, diarrhoea, nausea, abdominal pain, hepatic enzyme increased, rash, musculoskeletal pain, arthralgia, fatigue, pruritus. **Common (≥1 to <10%):** Lower respiratory tract infection, influenza, decreased appetite, hyperglycaemia, vision blurred, dry eye, palpitations, pleural effusion, dyspnoea, non-cardiac chest pain, pancreatitis, blood bilirubin increased, urticaria, pyrexia, oedema, blood creatine phosphokinase increased. **Uncommon (≥0.1 to <1%):** Febrile neutropenia, electrocardiogram QT prolonged, hypersensitivity. **Interactions:** ♦Caution recommended with medicinal products with known risk of *torsades de pointes*. ♦Caution recommended with strong CYP3A4 inducers. ♦Caution recommended with CYP3A4 substrates with narrow therapeutic index. ♦Caution recommended with CYP2C9 substrates with narrow therapeutic index. ♦Caution recommended with substrates of OATP1B, BCRP or both transporters, including, but not limited to sulfasalazine, methotrexate, pravastatin, atorvastatin, pitavastatin, rosuvastatin and simvastatin. **Packs:** 20mg, 40mg (60's). Not all pack sizes may be marketed. **Legal classification:** P1S1S3

References: 1. Scemblix Hong Kong Prescribing Information. **2.** Michael J. Mauro, et al. *Blood* 138(2021) 310-313. **3.** List of Registered Pharmaceutical Products, Pharmacy & Poison Board of Hong Kong, Department of Health. Accessed on Mar 2024 **4.** O'Brien SG, Guilhot F, Larson RA, et al. *N Engl J Med.* 2003;348(11):994-1004. **5.** Saglio G, Kim D-W, Issaragrisil S, et al. *N Engl J Med.* 2010;362[24]:2251-2259. **6.** Kantarjian H, Shah NP, Hochhaus A, et al. *N Engl J Med.* 2010;362[24]:2260-2270. **7.** ortes JE, Gambacorti-Passerini C, Deininger MW, et al. *J Clin Oncol.* 2018;36(3):231-237. **8.** Kantarjian HM, Giles FJ, Bhalla KN, et al. *Blood.* 2011;117(4):1141-1145. **9.** Cortes JE, Kantarjian HM, Brummendorf TH, et al. *Blood* 2011;118(17):4567-4576. **10.** Shah NP, Kantarjian HM, Kim D-W, et al. *J Clin Oncol.* 2008;26(19):3204-3212. **11.** Andrea Hocchaus, et al. *Leukemia;* https://doi.org/10.1038/s41375-023-01829-9.

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SCEMBLIX® (asciminib)