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ViiV Healthcare wins Japanese approval for Dovato to treat HIV-1

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Dovato (dolutegravir 50 mg/lamivudine 300 mg) gets approval from the Japan Ministry of Health, Labour andWelfare (MHLW) for the treatment of HIV-1 infection in adults and adolescents above 12 years of age weighing at least 40 kg

ViiV Healthcare, the global specialist HIV company majority owned by GSK, with Pfizer Inc. and Shionogi Limited as shareholders, announced that it has obtained approval of Dovato (dolutegravir 50 mg/lamivudine 300 mg) from the Japan Ministry of Health, Labour and Welfare (MHLW) for the treatment of HIV-1 infection in adults and adolescents above 12 years of age weighing at least 40 kg, to be administered orally, with or without food.

Dovato is a once-daily, single-pill, 2-drug regimen (2DR) for treatment-naïve HIV-1 infection that combines dolutegravir, an integrase inhibitor (INI), with the nucleoside reverse transcriptase inhibitor (NRTI) lamivudine.

Dustin Haines, President, ViiV Healthcare Japan said: “In Japan, the standard of care for treatment-naïve people living with HIV has been for many years with a three-drug regimen. The data from our dolutegravir-based 2-drug regimen development programme has, however, challenged this, and with the authorisation of Dovato, people living with HIV in Japan can, for the first time, start treatment on a once-daily, single-pill, 2-drug regimen with the knowledge that efficacy is non-inferior to a three-drug regimen.”

Dr. Ichiro Koga, MD, Director Medical Affairs, ViiV Healthcare Japan said: “The authorisation of Dovato in Japan marks a significant development for people living with HIV. This treatment allows individuals to take a 2-drug regimen in a once-daily, single-pill with dolutegravir at its core. ViiV Healthcare’s ambition and innovative R&D programme aims to reduce the number of HIV medicines people living with HIV take over a lifetime and Dovato is an important addition to our portfolio of medicines to help support this aim.”