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Singapore: Initial results received from the phase III SINGLE (ING114467) study of Shionogi-ViiV Healthcare's investigational integrase inhibitor dolutegravir in treatment-naive adults with HIV-1 demonstrated superiority of the dolutegravir-based regimen compared to the single tablet regimen Atripla. The Shionogi-ViiV Healthcare is a joint venture between Japanese firm Shionogi and ViiV Healthcare, a global company with a sole focus on HIV established in 2009 by GlaxoSmithKline and Pfizer.

Differences in efficacy were primarily driven by a higher rate of discontinuation due to adverse events on the Atripla arm. The SINGLE study was designed to demonstrate non-inferiority of the dolutegravir-based regimen versus Atripla, and the primary analysis met this criterion.

Statistical superiority was concluded as part of a subsequent, pre-specified testing procedure. SINGLE is an ongoing double blind, double dummy study designed to compare the efficacy and safety of two antiretroviral regimens: dolutegravir 50mg

plus abacavir/lamivudine (Kivexa/Epzicom) versus Atripla.

"Taken together with the results of the SPRING-2 trial, the SINGLE findings suggest that, if approved by regulators, a treatment regimen containing dolutegravir may offer people living with HIV an important additional first line option in the future," said Dr Tsutae 'Den' Nagata, chief medical officer, Shionogi.

"This study represents an important milestone in the development of dolutegravir-based regimens, including a single-tablet regimen, and also for the Shionogi-ViiV Healthcare joint venture. We look forward to receiving further safety and efficacy data from two phase III studies in treatment experienced patients to continue to build a comprehensive picture of the role of dolutegravir in the treatment of HIV," said Dr John Pottage, chief medical officer, ViiV Healthcare.

Full results of this study, including key secondary endpoints, will be presented at upcoming scientific meetings. SINGLE is the second of four Phase III studies that are due to be reported in 2012. Data from the clinical trial SPRING-2 (ING113086) were announced in April 2012. Data from VIKING-3 (ING112574) and SAILING (ING111762) in treatment-experienced patients will be received later this year and will allow further characterization of the profile of dolutegravir. These studies are designed to support a future regulatory filing for dolutegravir.