



MEMORANDUM

Hanmi Pharmaceuticals advances new once-weekly insulin candidate into phase 1 - February 17, 2015

Last week, Korea-based Hanmi Pharmaceuticals [announced](#) the initiation of phase 1 clinical testing of its new once-weekly basal insulin candidate LAPSInsulin-115 (formerly HM12470). The announcement is slightly behind [guidance](#) in the middle of 2014 for global phase 1 to begin by the end of 2014. The series of [single ascending dose studies](#) will test the candidate's safety, tolerability, and PK/PD profile in 48 type 2 diabetes patients and 48 type 1 diabetes patients. Hanmi's weekly insulin program involved two candidates; a [ClinicalTrials.gov page](#) for a phase 1 program for the other candidate (HM12460A) was first registered back in 2012 and was expected to be completed in February 2014, although it has not been updated over the past year; given the decision to move forward with HM12470 and the new candidate's superior profile we imagine development of the previous candidate may be on hold. [Preclinical data](#) on HM12470 showed a longer action profile than Novo Nordisk's Tresiba (insulin degludec), PEGylated insulin, and HM12460A. Other companies developing once-weekly insulins include Novo Nordisk and PhaseBio (phase 1) as well as [AntriaBio](#) (phase 1 initiation expected in 2H15). The insulin market promises to be quite dynamic moving forward, with lots of moving parts in the \$22-plus billion global insulin market (this has more than doubled since 2007). The sheer influx of more patients being diagnosed earlier and living longer is a positive for the market, while better orals have prompted a delay to insulin, especially traditional MDI - as have better GLP-1s, a class in which we expect a resurgence with easier to use and easier to prescribe products. Biosimilar insulin entry will mix things up further, as will oral and injected fixed dose combinations. Pricing pressure for all products in the US, especially those that are harder to differentiate is clearly here to stay, however, and that will have a trickle down effect globally. We doubt we will see double digit growth of 2013 and earlier years in the insulin market for some time, if ever.