Merck submits once-weekly DPP-4 inhibitor omarigliptin in Japan - November 26, 2014

Merck announced earlier this week that it has submitted a New Drug Application in Japan for its once-weekly DPP-4 inhibitor omarigliptin. We saw positive phase 3 results at EASD demonstrating comparable safety and efficacy with omarigliptin and Merck's once-daily DPP-4 inhibitor Januvia (sitagliptin); both products achieved placebo-adjusted A1c reductions of ~0.8% from a mean baseline of 8% with no meaningful differences in adverse events. Given the comparable clinical profiles, frequency of administration stands to be the primary point of differentiation between the products, and we imagine that many (though perhaps not all) patients will view the convenience of once-weekly administration as a meaningful advantage - we certainly believe it has the potential to improve adherence to treatment for some patients. The Japanese submission is Merck's first regulatory filing for omarigliptin - Japan may have been a priority due to the high popularity of DPP-4 inhibitors there. Merck plans to submit the product in additional geographies in the future. Omarigliptin's global phase 3 program includes nine trials involving a total of ~7,500 patients with type 2 diabetes. Most of the ongoing global phase 3 trials for omarigliptin are projected to end in 2015 to early 2016, with a CVOT slated to end in late 2017, providing clues on the timeline for possible US/EU submissions. In global terms, Merck is currently the dominant player in the once-weekly DPP-4 inhibitor arena - Takeda submitted its once-weekly candidate trelagliptin in Japan in March (a decision is expected by March 2015) but opted to discontinue development in the US and EU due to prohibitive development costs.