



MEMORANDUM

**Novo Nordisk's Fiasp (faster-acting insulin aspart) launches in Canada -
March 27, 2017**

Novo Nordisk [announced](#) this morning that Fiasp (faster-acting insulin aspart) is now available in Canada, following Health Canada marketing authorization on [January 6](#). This is the first official launch of Fiasp globally - and the first launch of any next-generation prandial insulin, for that matter - though the product was also [EMA-approved](#) in early January. We learned at [Diabetes UK](#) that the company aims to roll-out the product swiftly in European countries - the official UK launch date is set for April 10, but Fiasp was already on wholesalers' shelves as of February 27. Also upcoming is Novo Nordisk's planned [resubmission](#) of Fiasp to the FDA. The company received a [Complete Response Letter](#) (CRL) in October 2016 for the drug upon initial filing, but management expressed a positive outlook on prospects for US approval by end of 2017 during the recent [4Q16 earnings call](#), explaining how Novo Nordisk and the FDA had a "constructive" meeting following the CRL and reached an agreement on next steps and additional data (said to be already available).

We're thrilled that an advanced mealtime insulin with faster onset and offset is finally available to patients - we've been eager to see Fiasp reach the market since phase 3 data from Onset 1, 2, and 3 was presented at [ADA 2016](#). While some view the results from the Onset program as demonstrating a somewhat incremental rather than truly disruptive A1c benefit vs. NovoLog (insulin aspart), we'll take incremental - we maintain that any improvement in mealtime insulin could be hugely impactful for patients living in the real world, in minimizing postprandial glucose excursions and reducing hypoglycemia risk. Moreover, we're very interested to see how faster-acting aspart performs in insulin pumps and automated insulin delivery systems. Naturally, price is the next big question on our minds. Novo Nordisk reps at Diabetes UK [suggested](#) that the product will be priced on par with the NovoRapid FlexPen in the UK - this would be a huge plus from an access perspective. We'll have to wait and see if this pricing holds true in Canada, in other European nations, and eventually in the US, where controversy continues to swirl over insulin pricing.

-- by Payal Marathe, Helen Gao, and Kelly Close