



MEMORANDUM

Zealand reports positive topline phase 3 results for HypoPal glucagon rescue pen - May 15, 2019

Confirms safety and efficacy with autoinjector, same time to recovery (10-min) as [pivotal trial](#) with pre-filled syringe; Pediatric results delayed to September 2019, pushing back NDA from 4Q19 to early 2020

Zealand yesterday reported positive [topline results](#) from its [phase 3 confirmatory trial](#) (n=45) for liquid-stable glucagon dasiglucagon, verifying its efficacy in the HypoPal autoinjector for emergency hypoglycemia rescue. The HypoPal rescue pen met all primary and secondary endpoints of the trial.

The median time to blood glucose recovery (defined as the first increase of ≥ 20 mg/dL) was 10 minutes, 25 minutes faster than placebo ($p < 0.001$) and identical to that observed in the [pivotal phase 3 trial](#) testing dasiglucagon in a pre-filled syringe.

There were no safety concerns with the HypoPal. Dasiglucagon rates of nausea (62%) and vomiting (29%) were similar to placebo (55% and 23%, respectively).

With this result, only three studies remain between dasiglucagon and an NDA submission: (i) a phase 3 [pediatric study](#) (ages 6-17); (ii) a regulatory-required [study](#) testing the PK of dasiglucagon administered via IV; and (iii) a technical study to expand the room temperature shelf life of dasiglucagon. **Notably, Zealand CMDO Dr. Adam Steensberg states in the company's [announcement](#)** that results from the pediatric trial have been delayed to September 2019 due to recruitment difficulties, pushing back projected NDA filing for the HypoPal from 4Q19 to early 2020.

Zealand will give its 1Q19 update tomorrow morning, at which point we hope to have more clarity on this timeline. We also expect management to again underscore dasiglucagon's faster onset compared to Xeris' Glucagon Rescue Pen (anticipated [4Q19 US launch](#)) and Lilly's nasal glucagon (FDA review extended to [3Q19](#)), given that this confirmatory study corroborated the [pivotal trial's](#) 10-minute recovery. This area has a massive unmet need - the current strategy for emergency hypoglycemia rescue are dismal and we see lots of growth opportunities in this area, and although there is a lot of competition coming, this small market could expand dramatically. Longer term, we hope there is less need for this product, but we don't see that happening anytime soon.

--by Peter Rentzepis, Martin Kurian, and Kelly Close