CLOSER LOOK

MEMORANDUM

Approval of semaglutide would be a big win for patients with type 2 diabetes and promote awareness of and access to the GLP-1 agonist class - October 18, 2017

Executive Highlights

- Our therapy associate Ms. Ann Carracher spoke in favor of approval for Novo Nordisk's once-weekly GLP-1 agonist semaglutide at the October 18 EMDAC meeting. See the full text of her remarks below!

Good afternoon, and thank you to the chairperson and committee for this opportunity to speak on what I believe would be a groundbreaking development for people with diabetes. My name is Ann Carracher; I am an associate at Close Concerns, and I am here to speak on behalf of The diaTribe Foundation, a nonprofit organization founded to improve the lives of people with diabetes, prediabetes, and obesity, and to advocate for action. diaTribe, the Foundation's patient-focused online publication, is subscribed to by over 130 thousand people with diabetes and generates approximately 2.5 million page views per year. However, only 0.5% of those page views go to articles focused on GLP-1 agonists, underscoring the need for more awareness among both patients and their prescribing physicians of the benefits of GLP-1 agonists.

We believe that semaglutide, with a superior efficacy profile and patient friendly once-weekly dosing, is a truly disruptive candidate that would go a long way in making both patients and providers more aware of the benefit of this class.

By Close Concerns' calculations, the GLP-1 agonist class grew 25% in 2016 to reach $5 billion in sales, and is on track to hit $6 billion in 2017. Despite impressive financial results, however, a 2013 Diabetes Care paper found that only 5% of patients with type 2 diabetes in the US were prescribed a GLP-1 agonist. This number has, of course, grown significantly since 2013, but the barriers to GLP-1 agonist treatment remain the same: high cost, lower-than-optimal reimbursement, and a lack of patient friendliness, largely due to frequent and sometimes complication injections. Notably, Victoza has maintained market leader status by revenue since its inception, despite once-daily dosing. I would ask you to consider, then, a GLP-1 agonist with a new level of efficacy compared to existing GLP-1 agonists, both in glycemic and weight loss benefits - giving an average A1c drop of 1.8% and weight loss of 10 to 14 pounds in SUSTAIN 7 - all with once weekly dosing.

Semaglutide could be a huge win for patients with type 2 diabetes, not to mention obesity and even prediabetes down the line. Semaglutide would join exenatide and dulaglutide as a once-weekly formulation, but the data show that it simply performs better as a GLP-1 agonist. It balances efficacy and patient friendliness in a way that no GLP-1 agonist has before. As far as injectable therapies go, semaglutide is also simpler to prescribe and dose than insulin and fixed ratio combinations, making it provider friendly as well.

Moreover, more choices are better for patients and patient access. Assuming pricing similar to Victoza, we would imagine a high level of interest from patients and providers. Perhaps most importantly, patient satisfaction and ease of use promote adherence; in a theoretical world, high adherence encourages reimbursement, meaning more patients can access breakthrough therapies like semaglutide. Traditionally, the FDA has not concerned itself with matters of patient access - still, we've recently seen Commissioner Gottlieb introduce the Drug Competition Action Plan with the goal of improving consumer access to medications. In this environment, the patient access implications of another, truly disruptive GLP-1 agonist should not be ignored. We fully believe semaglutide will shake up the GLP-1 class for the better, and strongly encourage the committee to consider the benefit this would have for patients.

I am looking forward to the rest of the day's discussion, and thank you again for this opportunity.

-- by Ann Carracher and Kelly Close