BioSpectrum the business of Bio & Health Sciences

Rybelsus by Novo Nordisk gets USFDA approval

23 September 2019 | News

Rybelsus® more effectively lowered blood sugar than sitagliptin and empagliflozin

Novo Nordisk has announced that the USFDA approval for Rybelsus® (semaglutide tablets), as an adjunct to diet and exercise to improve glycaemic control in adults with type 2 diabetes mellitus.

Rybelsus®, the brand name for oral semaglutide in the US, is the first approved glucagon-like peptide-1 (GLP-1) receptor agonist in a tablet. The approval of Rybelsus® is based on the results from 10 PIONEER clinical trials which included 9,543 adults with type 2 diabetes.

Rybelsus® more effectively lowered blood sugar than sitagliptin and empagliflozin. Furthermore, treatment with Rybelsus® resulted in up to 4.4 kg reduction in body weight. Rybelsus® demonstrated a safe and well-tolerated profile across the PIONEER programme, with the most common adverse event being mild to moderate nausea which diminished over time.

Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk said, “We are very excited that we can make the first oral GLP-1 available in the US and thereby expand the treatment options for adults living with type 2 diabetes. Novo Nordisk has a very long legacy of developing innovative injectable medicines for people living with diabetes and, with the approval of Rybelsus®, we are now able to bring our innovation into the market for oral antidiabetics.”

Novo Nordisk plans to make Rybelsus® available to adults with type 2 diabetes in the US in the fourth quarter of 2019.