EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

31 January 2020
EMA/CHMP/47090/2020
Media and Public Relations

Press release

First oral GLP-1 treatment for type 2 diabetes

EMA's human medicines committee (CHMP) has recommended granting a marketing authorization in the European Union (EU) for Rybelsus (semaglutide) for the treatment of adults with insufficiently controlled type 2 diabetes to improve glycaemic control as an adjunct to diet and exercise. It is the first glucagon-like peptide (GLP-1) receptor agonist treatment - a class of non-insulin medicines for people with type 2 diabetes - developed for oral use, providing patients with another option to treat the disease without injections.

Type 2 diabetes is a disease in which the pancreas does not make enough insulin to control the level of glucose in the blood or when the body is unable to use insulin effectively. Most people with diabetes have this form of diabetes. Possible complications of diabetes include heart attack, stroke, kidney failure, leg amputation, vision loss and nerve damage.

The active substance in Rybelsus, semaglutide, acts in the same way as the incretin hormone GLP1: it reduces blood glucose by stimulating pancreatic secretion of insulin and lowering the secretion of glucagon (a hormone that works to raise blood sugar concentration) when blood sugar is high.

The safety and efficacy of Rybelsus were studied in eight clinical trials that included patients at various stages of the disease. In three of these studies, Rybelsus was compared to a placebo. In the development program, it was either used on its own, added to the standard treatment or compared to an injection treatment of its same class (GLP-1 receptor agonist).

The most common side effects observed during the clinical trials were gastrointestinal side effects, such as nausea and diarrhoea. Hypoglycaemia may occur when used in combination with insulin or sulphonylurea.

The opinion adopted by the CHMP is an intermediary step on Rybelsus's path to patient access. The CHMP opinion will now be sent to the European Commission for the adoption of a decision on an EU-wide marketing authorisation. Once a marketing authorisation has been granted, decisions about price and reimbursement will take place at the level of each Member State, taking into account the potential role/use of this medicine in the context of the national health system of that country.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The applicant for Rybelsus is Novo Nordisk A/S.

3. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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