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Press release

First oral add-on treatment to insulin for treatment of certain patients with type 1 diabetes

EMA's human medicines committee (CHMP) has recommended for the first time an adjunct treatment to insulin in the form of a tablet for certain patients with type 1 diabetes mellitus.

Dapagliflozin is already authorised in the European Union as Forxiga and Edistride[1] for the treatment of patients with type 2 diabetes. It belongs to a new generation of diabetes medicines called selective SGLT2 inhibitors that work in the kidneys to prevent reabsorption of glucose from the urine into the blood stream. This helps lower the blood sugar level. Following an assessment of data from new clinical trials, the CHMP is now recommending to extend the indication of dapagliflozin to certain patients with type 1 diabetes mellitus, when their insulin alone does not provide adequate control of their blood glucose levels despite optimal insulin therapy. Patients considered for this treatment should fulfil certain requirements and should not have a body mass index (BMI) below 27 kg/m^2.

Type 1 diabetes is an autoimmune disease in which the immune system mistakenly attacks the insulin-producing beta cells in the pancreas. Without these beta cells, the body cannot maintain proper blood glucose levels in response to daily activities such as eating or exercise. Patients with type 1 diabetes require lifelong insulin therapy.

In spite of improvements in insulins, methods of administration and monitoring of blood glucose, a proportion of patients with the disease are unable to achieve or maintain recommended blood sugar levels with insulin alone. Hyper- and hypoglycaemia and weight gain are common and patients' life expectancy is still significantly reduced compared to the general population, mainly due to the increased risk of heart disease. Thus, there is a need for new therapies as an adjunct to insulin therapy, to better manage blood sugar levels and other cardiovascular risk factors.

The CHMP's positive opinion is based on data from two Phase III studies including 548 patients with type 1 diabetes mellitus. The main benefit of treatment with dapagliflozin in patients with type 1 diabetes is a combined effect on glycaemic control, weight reduction, effects on blood pressure and reduced variability of glucose levels.

[1] Edistride is a duplicate of Forxiga.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 8427 **Facsimile** +44 (0)20 3660 5555
E-mail press@ema.europa.eu **Website** www.ema.europa.eu

The data presented with this application also show that despite precautionary measures, there is a considerable increase in the risk of diabetic ketoacidosis (DKA), a potentially life-threatening complication. Because the increased risk is of concern, the CHMP recommends limiting the use in type 1 diabetes mellitus patients as follows: treatment should only be considered in overweight or obese patients with a BMI ≥27 kg/m^2. Use of dapagliflozin is not recommended in type 1 diabetes mellitus patients with low insulin requirement. During treatment with dapagliflozin, insulin therapy should be continuously optimised to prevent ketosis and DKA and the insulin dose should only be reduced to avoid hypoglycaemia. This treatment should only be initiated and supervised by specialist doctors. Patients should be able and committed to control ketone levels in their body. They should be educated about risk factors for DKA and how to recognise its signs and symptoms.

The opinion adopted by the CHMP is an intermediary step on Forxiga/Edistride's path to patient access in this new indication. 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 Edistride and Forxiga is AstraZeneca AB.
3. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

Contact our press officers

Tel. +44 (0)20 3660 8427
E-mail: press@ema.europa.eu
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