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Media and Public Relations

Press release

New treatment for children with type 2 diabetes

EMA's human medicines committee (CHMP) has recommended granting an extension of indication to Victoza (liraglutide) to include the treatment of children and adolescents aged 10 years or older with type 2 diabetes. This medicine is already approved for use together with diet and exercise in adults with type 2 diabetes, on its own or as an add-on to other diabetes medicines.

Type 2 diabetes is a chronic disease in which the pancreas does not make enough insulin to control the level of glucose (sugar) in the blood or when the body is unable to use insulin effectively. It can lead to serious complications if a person does not receive treatment. According to the World Health Organization, type 2 diabetes has increasingly been reported in children and adolescents recently, so much so that in some parts of the world type 2 diabetes has become the main type of diabetes in children.

The recommended treatment for paediatric type 2 diabetes is similar to that in adults, with emphasis on a step-wise approach starting with lifestyle modifications, particularly healthy eating and exercise, followed by the use of a single medical therapy and later by two therapies in combination. The aim is that the patient achieves and maintains low levels of glucose in the blood in order to prevent long-term complications.

Currently, the only two approved treatment options for paediatric type 2 diabetes patients in most countries are metformin and insulin. However, more than half of young patients do not achieve glycaemic control on metformin alone, even when combined with lifestyle interventions, and treatment with insulin has considerable side effects such as weight gain, or a high risk of hypoglycaemia. Therefore, there is a medical need for alternative treatment options for children and adolescents with type 2 diabetes.

Victoza is the first non-insulin, besides metformin, to get a positive opinion for paediatric use for type 2 diabetes. The active substance in Victoza, liraglutide, is an 'incretin mimetic'. This means that it acts in the same way as incretins, a group of metabolic hormones that stimulate an increase of the amount of insulin released by the pancreas in response to food. This helps with the control of blood glucose levels. Liraglutide has been used in adults for approximately ten years, so there is an extensive amount of data available in particular with regards to safety.

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The efficacy and safety of Victoza in children and adolescents was investigated in a placebo-controlled trial with 134 patients with type 2 diabetes aged 10 – 17 years. This study was carried out in accordance with a Paediatric Investigation Plan (PIP), which was agreed by the Agency's Paediatric Committee (PDCO).

The study compared patients in the liraglutide group with a placebo group over 26 weeks. Patients treated with Victoza, with or without insulin, experienced a clinically relevant reduction in the levels of glycated haemoglobin (HbA1c) that is measured via a blood test to evaluate average blood sugar levels in a patient over a period of weeks or months. A higher number of patients experienced hypoglycaemic episodes in the liraglutide group than in the placebo group irrespective of prior insulin use.

The results of the trial demonstrated that the safety profile of Victoza in this population is comparable to that in adults. The most common side effects were nausea, vomiting, diarrhoea, headache and abdominal pain.

The opinion adopted by the CHMP is an intermediary step on Victoza'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 Victoza 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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