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## Press release

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# New add-on treatment to insulin for treatment of certain patients with type 1 diabetes

EMA's human medicines committee (CHMP) has adopted a positive opinion for Zynquista (sotagliflozin) intended as an adjunct to insulin for certain patients with type 1 diabetes mellitus.

Zynquista is a small molecule with dual inhibitor activity on SGLT1 and SGLT2. It works in the kidneys to prevent reabsorption of glucose from the urine and in the proximal intestine to delay and reduce glucose absorption into the blood stream, which helps lower the blood sugar level. This medicine is the second SGLT inhibitor for the treatment of type 1 diabetes to be recommended for authorisation.

Zynquista is indicated as an adjunct to insulin therapy to improve glycaemic control in adults with type 1 diabetes mellitus who have failed to achieve adequate glycaemic control despite optimal insulin therapy. Patients considered for this treatment should fulfill certain requirements and should have a body mass index (BMI) higher than 27 kg/m<sup>2</sup>.

Type 1 diabetes is an autoimmune disease in which the immune system mistakenly attacks the insulin-producing beta cells in the pancreas. Without insulin, the body cannot maintain proper blood glucose levels. Patients with type 1 diabetes require lifelong insulin therapy.

In spite of improvements in insulin, its 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 three phase 3 studies including 1,853 patients with type 1 diabetes mellitus. The main benefit of treatment with sotagliflozin in patients with type 1 diabetes is its ability to improve glycaemic control. Other effects include weight and blood pressure reductions and reduced variability of glucose levels.

Despite precautionary measures during treatment with sotagliflozin, 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 higher than 27 kg/m<sup>2</sup>. Use of Zynquista is not recommended in type 1 diabetes mellitus patients with low insulin requirements. During treatment with Zynquista, 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 Zynquista'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**

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1. The applicant for Zynquista is sanofi-aventis groupe.
2. More information on the work of the European Medicines Agency can be found on its website: [www.ema.europa.eu](http://www.ema.europa.eu)

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