28 February 2019
EMA/CHMP/138211/2019
Committee for Medicinal Products for Human Use (CHMP)

**Summary of opinion[1] (initial authorisation)**

# Zynquista

## sotagliflozin



On 28 February 2019, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Zynquista, intended for the treatment of type 1 diabetes mellitus as an adjunct to insulin. The applicant for this medicinal product is sanofi-aventis groupe.

Zynquista will be available as 200 mg film-coated tablets. The active substance of Zynquista is sotagliflozin, a blood glucose lowering agent (ATC code: A10BK). Sotagliflozin works by blocking proteins in the intestine and the kidney called sodium-glucose co-transporter-1 and -2 (SGLT1 and SGLT2). This delays and reduces glucose absorption in the intestine and glucose re-absorption in the kidney, where it also leads to glucose excretion in the urine.

The main benefit with Zynquista is its ability to improve glycaemic control. Other effects include weight and blood pressure reductions and reduced variability of glucose levels. The most common side effects are genital mycotic infections, diabetic ketoacidosis and diarrhoea.

The full indication is: "Zynquista is indicated as an adjunct to insulin therapy to improve glycaemic control in adults with type 1 diabetes mellitus with a Body Mass Index (BMI) ≥ 27 kg/m$^2$, who have failed to achieve adequate glycaemic control despite optimal insulin therapy." It is proposed that the treatment with Zynquista be initiated and supervised by physicians experienced in the treatment of type 1 diabetes mellitus.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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