Subject: CI update
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From: Robert Stoekenbroek
To: Metsera
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Metsera Reports

October 30, 2023

Safety updates

EMA panel concludes that available evidence does not support link between GLP-1RAs and thyroid cancer

Summary and Implications

- European Medicines Agency safety panel did not find a causal link between GLP-1 receptor agonists and thyroid cancer after a months-long review.
- Concerns were initially raised following publication of a case-control study, which seemed to support observations of an increased risk in rodent studies for which the human relevance was unknown at the time.

Context

The European Medicines Agency (EMA)'s Pharmacovigilance Risk Assessment Committee (PRAC) began assessing this safety signal in January 2023 following the publication of a French case-control study suggesting that there might be an increased risk of thyroid cancer with the use of these medicines in patients with T2DM.

In the United States, GLP-1RAs carry a black box warning indicating that “In rodents, [GLP-1RAs] cause[s] thyroid C-cell tumors. It is unknown whether [GLP-1RAs] cause[s] thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans as the human relevance of [GLP-1RA]-induced rodent thyroid C-cell tumors has not been determined.”

Content

The safety committee concluded a review of published literature, including observational studies, as well as cumulative data submitted by the marketing authorization holders (MAHs) which included non-clinical, clinical and post-marketing data. At present, the PRAC considers that no updates to the product information are warranted based on the available data.

In July, PRAC also began reviewing GLP-1RAs for suicidality after passive monitoring systems flagged about 150 reports of suicidal thinking. The results of that evaluation are also expected in the next few months.

POPULATION HEALTH PARTNERS

Robert Stoekenbroek | +1-908-206-6357

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