COLLEGE TER BEOORDELING VAN GENEESMIDDELEN

# Public Assessment Report

# Scientific discussion

# Egotux 12.5 mg, 25 mg, 37.5 mg and 50 mg, hard capsules (sunitinib)

## NL/H/5250/001-004/DC

## Date: 25 May 2023

**This module reflects the scientific discussion for the non-approval of Egotux 12.5 mg, 25 mg, 37.5 mg and 50 mg, hard capsules. The procedure was finalised on 17 September 2021.**

# I. INTRODUCTION

Based on the review of the quality, safety and efficacy data, the Member States have refused a marketing authorisation for Egotux 12.5 mg, 25 mg, 37.5 mg and 50 mg, hard capsules from Genepharm S.A.

The indications applied for included the treatment of:

- unresectable and/or metastatic malignant gastrointestinal stromal tumour (GIST) in adults after failure of imatinib treatment due to resistance or intolerance.
- advanced/metastatic renal cell carcinoma (MRCC) in adults.
- unresectable or metastatic, well-differentiated pancreatic neuroendocrine tumours (pNET) with disease progression in adults.

The concerned member state (CMS) involved in this procedure was Greece.

The marketing authorisation was applied for pursuant to Article 10(1) of Directive 2001/83/EC, claiming essential similarity between the new product and the innovator product Sutent which has been registered in the EEA via a centralised procedure (EU/1/06/347).

The application was discussed in the Board meeting of 26 August 2001. For further details, please refer to the CBG-MEB website, public minutes from the meetings, Openbaar verslag 985e Collegevergadering.

# II. OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

The marketing authorisation could not be granted due to major objections qualifying as potential serious risk to public health as defined in the Guideline on the definition of a potential serious risk to public health in the context of Article 29(1) and (2) of Directive 2001/83/EC — March 2006 (2006/C 133/05):

<u>Clinical aspects</u>
Essential similarity between the new product (which contains sunitinib base as drug substance) and the reference product Sutent (which contains sunitinib malate as drug substance) was not sufficiently demonstrated since:

- The question of the effect of food on the bioavailability of the product has yet to be resolved. The new product and the reference product use a different sunitinib salt and differ in solubility. There are indications that sunitinib base is significantly less soluble than sunitinib malate at pH 6.8. Food intake increases the pH in the stomach and may have an effect on the absorption of the sunitinib base. Hence, pharmacokinetic data from a bioequivalence study under fed conditions should have been provided.

Therefore, the Board concluded that the marketing authorisation for Egotux 12.5 mg, 25 mg, 37.5 mg and 50 mg, hard capsules cannot be granted. Agreement on this conclusion was reached with the concerned member state. The decentralised procedure was finalised with a negative outcome on 17 September 2021.