RAVIMIAMET

Global Study Operations
Amgen AB
Gustav III:s Boulevard 54
Box 706
169 27 Solna
SWEDEN

02.08.2024 nr RKU-4/55

DECISION

to grant authorisation for clinical trial on the basis of Regulation (EU) No 536/2014 of the European Parliament and of the council

State Agency of Medicines has received the application from sponsor Amgen Inc. on 08.04.2024 to conduct a clinical trial under the conditions stipulated in Regulation (EU) No 536/2014 art 5 (1) and § 99^1 (1) of Estonian Medicinal Products Act (MPA).

Based on art 8 of Regulation (EU) No 536/2014, considering the aspects covered by Part I and Part II of the assessment report, on the basis of § 99^6 section 1 p 2 and (3) of Medicinal Product Act

State Agency of Medicines has decided to give the approval to conduct the clinical study protocol no 20210081 under the following conditions:

protocol no: 20210081 (Version 3, dated January 29, 2024; protocol supplement for European Union version 2, dated July 18, 2024)

full title of the trial: Phase 3 Multicenter, Randomized, Open-label, Active-controlled Study of Sotorasib, Panitumumab and FOLFIRI Versus FOLFIRI With or Without Bevacizumab-awwb for Treatment-naïve Subjects With Metastatic Colorectal Cancer With KRAS p.G12C Mutation (CodeBreaK 301)

sponsor of the trial: Amgen Inc.

number of subjects in Estonia: 3

starting date: August 2024

principal investigators and study locations:

- Dr Anneli Elme, North Estonia Medical Centre Foundation, J. Sütiste tee 19, 13419 Tallinn, Estonia

The addressee may file a challenge with State Agency of Medicines within 30 days as of the day when the addressee became or should have become aware of the decision as prescribed in Code of Administrative Procedure § 71(1). If the addressee wishes to have the decision to

annulled by the administrative court, he or she may submit a complaint to the Tartu Administrative Court as prescribed in § 7(1) and § 46(1) of the Code of Administrative Court Procedure within 30 days after the date on which the decision was notified to the applicant.

(digitally signed)

Katrin Kiisk
Director General