RAVIMIAMET

Derek Moriarty
GlaxoSmithKline Biologicals
12 River Walk, Citywest Business Campus
D24 YK11 Dublin
IRELAND

14.06.2024 nr RKU-4/38

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 GlaxoSmithKline Biologicals on 23.02.2024 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 1 and (3) of Medicinal Product Act

State Agency of Medicines has decided to give the approval to conduct the clinical study protocol no 222090 under the following conditions:

protocol no: 222090 (Version 1, dated 05/12/2023)

full title of the trial: A phase 3b, randomized, open label, multi-country, multi-center, extension and crossover vaccination study to evaluate the immunogenicity and safety of different revaccination schedules and persistence of a single dose of the RSVPreF3 OA vaccine in adults aged 60 years and above who participated in the RSV OA=ADJ-006 study

sponsor of the trial: GlaxoSmithKline Biologicals

number of subjects in Estonia: 429

starting date: August 2024

principal investigators and study locations:
- Dr Ingrid Alt, Vee Perearstikeskus OÜ, Vee tn 6, 72713 Paide, Estonia
- Dr Ivo Valter, Center for Clinical and Basic Research AS, J. Pärna tn 4, 10128 Tallinn, Estonia
- Dr Jaak Tälli, Innomedica OÜ, Narva mnt 7, 10117 Tallinn, Estonia
- Dr Riin Lanno, Merelahe TK OÜ, Paldiski mnt 68a, 10617 Tallinn, Estonia
- Dr Rain Jõgi, Tartu University Hospital, L. Puusepa tn 8, 50406 Tartu, Estonia

- Dr Andres Siig, Aktsiaselts Medicum Tervishoiuteenused, Punane tn 61, 13619 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