RAVIMIAMET

Clinical Project Manager
Chiesi Farmaceutici S.p.A.
Via Palermo 26 A
43122 Parma
ITALY

23.08.2024 nr RKU-4/62

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 Chiesi Farmaceutici S.p.A. on 23.07.2024 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 CLI-06001AA1-05 under the following conditions:

protocol no: CLI-06001AA1-05 (Version 5.0 EU, dated April 05, 2024)

full title of the trial: A 52-week, randomized, double-blind, double-dummy, placebo- and active- controlled (Roflumilast, Daliresp® 500µg), parallel group, study to evaluate the efficacy and safety of two doses of CHF6001 DPI add-on to maintenance triple therapy in subjects with Chronic Obstructive Pulmonary Disease (COPD) and chronic bronchitis

sponsor of the trial: Chiesi Farmaceutici S.p.A.

number of subjects in Estonia: 10

principal investigators and study locations:
- Dr Svetlana Sergejeva, North Estonia Medical Centre Foundation, J. Sütiste tee 19, 13419 Tallinn, Estonia
- Dr Veronika Iljina, Narva Hospital, Haigla 7, 20104 Narva, Estonia
- Dr Rain Jõgi, Tartu University Hospital, L. Puusepa tn 1a, 50406 Tartu, 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