



Central Committee on research Involving Human Subjects (CCMO)
Attn: Competent Authority
Parnassusplein 5
2511 VX Den Haag

Bennekom, 23 February 2021

Concerns: Digital submission of Early EoT notification
Protocol number: GLPG1690-CL-304
EudraCT number: 2018-001406-29
VHP number: VHP1350 (VHP2018114)
NL number: NL67478.078.18

Dear Members of the CCMO,

On behalf of the study sponsor, Galapagos NV (GLPG), we would herewith like to inform you of the early termination for the above-mentioned study GLPG1690-CL-304. GLPG1690-CL-304 is a Phase 3 study in development for the treatment of idiopathic pulmonary fibrosis. The study received the initial positive opinion on 03Apr2019 from the Ethics Committee and is initially authorized by the national Competent Authority on 06Dec2018 in the Netherlands.

The decision to prematurely terminate this trial is based on recommendations of the Independent Data Monitoring Committee (IDMC) made on 09-Feb-2021, which was the 6th unblinded review for the two phase 3 trials under the ziritaxestat program. Following this regular review of unblinded data, the IDMC concluded that:

- There was a safety concern identified with 600 mg
- There was a lack of efficacy signal in all arms of the study

The IDMC's conclusion is that ziritaxestat's benefit-risk profile no longer supports continuing the phase 3 studies. Following the IDMC recommendations all clinical trials within the ziritaxestat development program will be discontinued.

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All participating investigators were informed about the termination of the ISABELA studies on 10 February 2021.

The Sponsor recommendation to the Investigators is for study subjects to be discontinued from the study immediately. No new randomizations will take place and all patients in screening and in the study will be informed immediately. All scheduled screenings will be cancelled. For the randomized patients an End of Study Treatment (EOST) visit needs to be organized as soon as possible and a safety follow-up performed within a month after IMP discontinuation.

The End of Trial Notification Form is enclosed in this application. A press release letter, the communication letter to the participating sites and the letter to study patients are enclosed within the EC notification. The Sponsor provided the letter for patients to explain the reasons for study termination.

The clinical study summary report will be submitted to the applicable Ethics Committees and national Competent Authorities within one year after study end, in accordance with the requirements.

With this submission we declare that all relevant documents from the above-mentioned research dossier are signed by the authorised people. The signed documents are/will be submitted for review to the responsible review committee specified in question I1 of the general assessment and registration form (ABR form).

We would like to receive an acknowledgement of receipt. If you have any further questions about this submission, please contact 5.1.2.e +31 (0)318-655.1.2.e (tel.) or 5.1.2.e@ppdi.com.

Yours sincerely,

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Attachments :

A1. Cover Letter Application – NL67478.078.18 – Early EoT – 23Feb2021

B7. EudraCT End of Trial Form