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Dr Harald Enzmann
European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

30 October 2023

Subject: **Withdrawal of Marketing Authorisation Application for Vijoice® (alpelisib) 50 mg, 125 mg, and 200 mg film-coated tablets, EMEA/H/C/5468**

Dear Dr Enzmann,

I would like to inform you that Novartis has taken the decision to withdraw the marketing authorisation application for Vijoice® (alpelisib) 50 mg, 125 mg, and 200 mg film-coated tablets, which was intended to be used for the treatment of adult and paediatric patients aged 2 years and older with severe or life-threatening PIK3CA-related overgrowth spectrum (PROS) who require systemic therapy.

The withdrawal of the application is based on the time needed to acquire further data to support the benefit/risk assessment of Vijoice in the proposed indication. As PROS is a rare disease impacting paediatric and adult patients, the application for a conditional marketing authorisation was submitted on the basis of real-world evidence from a retrospective chart review study. As prospective data could not be provided to address the CHMP questions within the available procedural timeframe, the application is being withdrawn. Novartis intends to submit a new marketing authorization application once the prospective data become available. This withdrawal does not have any impact on the ongoing clinical trials with alpelisib.

Novartis is committed to further advancing the standard of care for patients with PROS and reserves the right to make further submissions at a future date in this or other therapeutic indications.

Novartis would like to sincerely thank the (Co-) Rapporteurs, EMA, PRAC, and the CHMP members for the time dedicated to reviewing this application.

I agree for this letter to be published on the EMA website.

Yours sincerely

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