10 December 2024

Prof. Bruno Sepodes
European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Subject: Withdrawal of Nugalviq (govorestat), 200 mg/ml oral suspension - EMEA/H/C/6270

Dear Prof. Bruno Sepodes,

I would like to inform you that, at this point of time, Advanz Pharma Limited has taken the decision to withdraw the application for Marketing Authorisation of Nugalviq (govorestat), 200 mg/ml oral suspension which was intended to be used for the treatment of adults and children aged 2 years and older with a confirmed diagnosis of classic galactosemia, also known as galactose-1-phosphate uridylyltransferase deficiency.

This withdrawal is based on the following reasons:

Advanz Pharma requires more time to acquire further data to support the assessment of Nugalviq in the proposed indication.

This withdrawal does not have any impact on the ongoing clinical trials and compassionate use programmes with govorestat.

We reserve the right to make further Marketing Authorisation Application submissions at a future date in this or other therapeutic indications.

Advanz Pharma would like to take this opportunity to thank the (Co-)Rapporteurs, Committee for Medicinal Products for Human Use (CHMP) and European Medicines Agency (EMA) for their time and consideration for this application.

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

Yours sincerely,

[redacted]

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