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Committee for Medicinal Products for Human Use (CHMP)
Attn: Prof. Bruno Sepodes
European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

6th Nov 2024

Subject: Withdrawal of Inaqovi, (decitabine / cedazuridine), 35 mg/100 mg, Film-coated tablet (EMEA/H/C/005823/II/02)

Dear Prof. Sepodes,

Otsuka Pharmaceutical Netherlands B.V. (hereinafter Otsuka) submitted a type II variation on 15 Dec 2023 to add treatment of adult patients with myelodysplastic syndromes and chronic myelomonocytic leukaemia to the indication of Inaqovi to European Medicines Agency.

We would like to inform you that, at this point in time, Otsuka has taken the decision to withdraw the application to add myelodysplastic syndromes for Inaqovi.

This withdrawal is based on the following reason:
Certain major objection from the CHMP cannot be fully addressed at this point in time.

Otsuka would like to sincerely thank the Rapporteurs, EMA, and CHMP members for the time dedicated to reviewing this application and the support provided during the process.

We reserve the right to make further submissions at a future date regarding this or other therapeutic indications.

The applicant agrees for this letter to be published on the EMA website.

Yours sincerely,

[redacted]

Otsuka Pharmaceutical Netherlands B.V.