Passion for Innovation.
Compassion for Patients.™

Daiichi-Sankyo

[redacted]

[redacted]

Professor B. Sepodes
European Medicines Agency
Product and Application Business Support
(PA-BUS)
Domenico Scarlattilaan 6
1083 HS Amsterdam

The Netherlands

20 December 2024

Withdrawal of Datroway, datopotamab deruxtecan, 100mg, powder for concentrate for solution for infusion
EMEA/H/C/006081/0000

Dear Professor Sepodes,

We would like to inform you that, at this point of time, Daiichi Sankyo Europe GmbH has taken the decision to withdraw the application for Marketing Authorisation of Datroway (datopotamab deruxtecan), 100mg, powder for concentrate for solution for infusion, which was intended to be used for the following indication:

> "Datroway as monotherapy is indicated for the treatment of adult patients with locally advanced or metastatic nonsquamous non-small cell lung cancer (NSCLC) who require systemic therapy following prior treatment:
> - Patients without known actionable genomic alterations previously treated with platinum-based chemotherapy in the advanced or metastatic setting and a PD-1 or PD-L1 inhibitor, either in combination or sequentially
> - Patients with actionable genomic alterations (as listed in section 5.1) previously treated with prior platinum-based therapy and targeted therapy for the detected alterations."

Daiichi Sankyo Europe GmbH has decided to discontinue this application because the major objection raised cannot be resolved within the timeframe.

The Company intends to continue development of this product and will continue to make datopotamab deruxtecan available to patients in ongoing clinical trials in NSCLC and other indications.

We remain fully committed to the development of datopotamab deruxtecan and reserve the right to make further Marketing Authorisation Application submissions at a future date in this or other therapeutic indication(s).

[redacted]

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

Yours sincerely,

[redacted]

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