Better Health, Brighter Future

Zurich, 18 November 2024

CONFIDENTIAL

CAT chair and CHMP chairman
CAT rapporteur and CHMP rapporteur
European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

RE: Withdrawal of type II variation for Alofisel grouped variation including the final results from trial ADMIRE-CD II - EMEA/H/C/004258

[redacted]

We would like to inform you that, at this time, Takeda Pharma A/S ("Takeda") will withdraw the grouped type II variation application, which includes the submission of final results of the Phase 3 ADMIRE-CD II trial, per Annex II condition of the Alofisel marketing authorization.

This withdrawal is based on interactions with the CAT indicating that the data provided thus far has been deemed insufficient, and it is not possible for Takeda to provide the additional efficacy data as expected by the EMA.

Takeda would like to sincerely thank the (Co-)Rapporteurs and the EMA for their time dedicated to reviewing this application and the helpful guidance provided during the review process.

We agree this letter can be published on the EMA website.

[redacted]

On behalf of Takeda Pharma A/S,

[redacted]