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September 12, 2023

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

Subject: Withdrawal of Jivadco (trastuzumab duocarmazine), 80 mg, powder for concentrate for solution for infusion - **EMEA/H/C/005654**

Dear Dr. Enzmann,

After careful consideration of the Day-180 response by CHMP, we would like to inform you that Medac Gesellschaft für klinische Spezialpräparate mbH as applicant withdraws the application for marketing authorisation of Jivadco® (trastuzumab duocarmazine), 80 mg, powder for concentrate for solution for infusion, which was intended to be used for the treatment of late stage HER2-positive metastatic breast cancer.

This withdrawal is based on the following reason:

- Feedback from CHMP on Day180 indicates that product is not approvable since "major objections" have been identified, which preclude a recommendation for marketing authorisation. To address the major objections additional information is needed and requires time and resources that extend beyond the current evaluation period.

All clinical trials with Jivadco have been finalized.

We reserve the right to make further submissions at a future date in this or other therapeutic indication(s).

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

On behalf of the applicant, yours sincerely,

Byondis B.V.