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European Medicines Agency
Domenico Scarlattilaan 6
1083HS Amsterdam
Netherlands

8th October 2021

Subject: ZYNYZ- retifanlimab MAA – EMEA/H/C/005632: Withdrawal of Marketing Authorisation Application

Dear Dr Enzmann,

We would like to inform you that, at this point in time, we have decided to withdraw the Marketing Authorisation Application for ZYNYZ (EMEA/H/C/005632) which was intended for the treatment of adult patients with locally advanced or metastatic squamous carcinoma of the anal canal.

Following the CHMP Day 120 List of Questions and the clarification meeting with the (Co)-Rapporteurs and EMA, we determined that we were not in a position to address satisfactorily the CHMP concerns.

The applicant reserves the right to submit further Marketing Authorisation Application at a future date in this or other therapeutic indication(s).

The withdrawal does not have any impact on ongoing clinical trials.

We would like to take this opportunity to thank the (Co)-Rapporteurs and EMA for their time reviewing this application.

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

Yours sincerely,

[redacted]