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Tomas Salmonson
CHMP Chair
European Medicines Agency (EMA)
30 Churchill Place
Canary Wharf
London, E14 5EU
United Kingdom

Munich, 10 July 2018

Withdrawal of Marketing Authorisation Application
Raligize (Axalimogene filolisbac) (H004473) – Advaxis, Inc.

Dear Dr. Salmonson,

On behalf of FGK Representative Services GmbH, located at Heimeranstrasse 35, 80339 Munich, Germany, who is the European Legal Representative of Advaxis Inc., located at 305 College Road East, Princeton, NJ 08540 USA, we herewith would like to inform you that the Applicant at this point has taken the decision to withdraw the application for Marketing Authorisation for Raligize (INN: axalimogene filolisbac).

Raligize is an Advanced Therapy Medicinal Product (ATMP), which was intended for the treatment of adult women who progress beyond first-line therapy of persistent, recurrent or metastatic carcinoma of the cervix.

The decision to withdraw the application is based on input received from the rapporteurs by the Committee for Advanced Therapies (CAT), indicating that results from the GOG-0265 Phase 2 study are unlikely to provide adequate support for conditional market authorization. While we believe the data are clinically meaningful, especially given the unmet medical need and historical data, we acknowledge the Committee's preliminary assessment of our application.

FGK and Advaxis would like to sincerely thank the (Co-)Rapporteurs, EMA, CAT and CHMP members for the time dedicated to reviewing this application and the support provided during the process.

This withdrawal does not have any impact on ongoing clinical trials with axalimogene filolisbac. FGK and Advaxis reserve the right to re-apply for the same indication at a future date.

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

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