



DLRC PHARMA SERVICES LTD

CHESTERFIELD HOUSE,
CLONMANNON,
ASHFORD,
COUNTY WICKLOW,
IRELAND

Dr. Harald Enzmann
Chair of the CHMP
European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Friday, 20 August 2021

**Subject: Withdrawal letter: Oportuzumab monatox DLRC Pharma Services
EMA/H/C/005730**

Dear Dr. Enzmann,

I would like to inform you that, at this point of time, DLRC Pharma Services has taken the decision to withdraw the application for Marketing Authorisation of **Oportuzumab monatox DLRC Pharma Services, 33 mg concentrate and solvent for intravesical solution**, which was intended to be used in adults for:

- the treatment and prevention of recurrence of carcinoma-in-situ (CIS) of the urinary bladder following transurethral resection in BCG-unresponsive patients.
- the prevention of recurrence of high-grade Ta and/or T1 papillary tumours following transurethral resection in BCG-unresponsive patients.

Sesen Bio Inc. submitted a BLA to FDA for oportuzumab monatox in parallel to the EMA MA Application. Following receipt of a Complete Response Letter from FDA, Sesen Bio is halting further regulatory activities relating to oportuzumab monatox in Europe until there is more clarity from the FDA on the next steps in the US. Therefore, the withdrawal is based on global regulatory priorities.

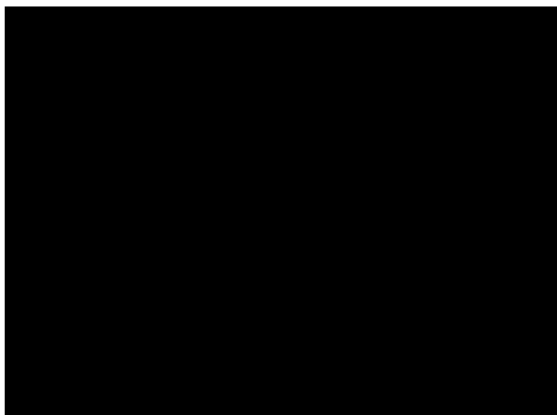
This withdrawal does not have any impact on any ongoing clinical trials.

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

The applicant DLRC Pharma Services and the sponsor of product development, Sesen Bio Inc., would like to take this opportunity to thank the CHMP and PRAC (Co-)Rapporteurs, CHMP and PRAC Members, and the EMA for the time and effort dedicated to their review of this application, and the guidance provided during the procedure

I agree for this letter to be published on the EMEA website.

Yours sincerely,



Person authorised for communication on behalf of the Applicant, DLRC Pharma Services Ltd., Ireland

CC: PTL, Rapporteur and Co-Rapporteur.