IOVANCE BIOTHERAPEUTICS

ADVANCING IMMUNO-ONCOLOGY

22 July 2025

Chair of the CHMP, Bruno Sepodes
European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Re: Amtagvi (lifileucel) 7.5 - 72 × 10^9 cells dispersion for infusion
Withdrawal of Marketing Authorisation Application

Applicant:	Iovance Biotherapeutics B.V.
Name of medicinal product(s):	Amtagvi (lifileucel)
Pharmaceutical form(s); strength(s):	7.5 - 72 × 10^9 cells dispersion for infusion
INN/active substance(s):	lifileucel (LN-144)
EMA Product Reference number	H0004741
ATC Code(s):	L01XL11

Dear Dr Sepodes,

I would like to inform you that Iovance Biotherapeutics B.V. (Iovance) has taken the decision to withdraw the application for Marketing Authorisation of Amtagvi (lifileucel) 7.5 - 72 × 10^9 cells dispersion for infusion, which was intended to be used for the treatment of adult patients with unresectable or metastatic melanoma previously treated with a PD-1 blocking antibody, and if BRAF V600 mutation positive, a BRAF inhibitor with or without a MEK inhibitor.

This withdrawal is based on the following reason: Iovance has taken this decision based on the CAT's view that the clinical data provided do not allow the committee to assess efficacy for Amtagvi at this time.

Iovance respectfully disagrees with the CATs assessment and considers that the totality of the scientific evidence demonstrates substantial efficacy, including the positive results from the pivotal C-144-01 study evaluating Amtagvi for the treatment of advanced melanoma who have received prior PD-1 blocking antibodies and if BRAF V600 mutation positive a BRAF inhibitor with or without a MEK inhibitor, and supports a positive benefit- risk assessment for Amtagvi in this population with a high unmet medical need and no other approved treatment options. Amtagvi is now a recommended treatment option in the NCCN and ESMO guidelines and is widely used in other countries.

This withdrawal does not have any impact on clinical trials with Amtagvi.

[redacted]

We would like to take the opportunity to thank the CAT Rapporteur and Co-Rapporteurs, CHMP and EMA for their time reviewing this application.

We reserve the right to make a further marketing authorisation application submission at a future date.

I agree for this letter to be published on the EMA website in a redacted manner.

Your sincerely,