insmed

Date: 8 June 2016

Dr Tomas Salmonson
CHMP Chairman
30 Churchill Place
Canary Wharf
London
E14 5EU
United Kingdom

Subject: Withdrawal of Arikayce™, liposomal amikacin, 590 mg, nebuliser suspension
EMEA product reference: **EMEA/H/C/003936**

Dear Dr Salmonson,

We would like to inform you that, at this point of time, Insmed Limited has taken the decision to withdraw the application for Marketing Authorisation of Arikayce, liposomal amikacin, 590 mg, nebuliser suspension, which was intended to be used for:

- Treatment of *Mycobacterium avium* Complex (MAC) lung disease in adults.

This withdrawal is based on:

Our understanding following the oral explanation that the CHMP considers that the data provided do not allow the Committee to conclude on a positive benefit risk for the proposed indication.

It is not expected that this withdrawal will have any consequences on ongoing clinical trials and compassionate use programmes.

We wish to recognize the tremendous insights we have gained during the thorough review process our product has undergone. Such perspective will directly guide our thinking as we continue in the Phase 3 development of this product. Accordingly, we acknowledge and sincerely thank the CHMP members and in particular our rapporteur and co-rapporteur for the support they have provided.

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

[redacted]