



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  
EMA product reference: **EMA/H/C/003936**

Dear Dr Salmonson,

We would like to inform you that, at this point of time, Insmmed 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.

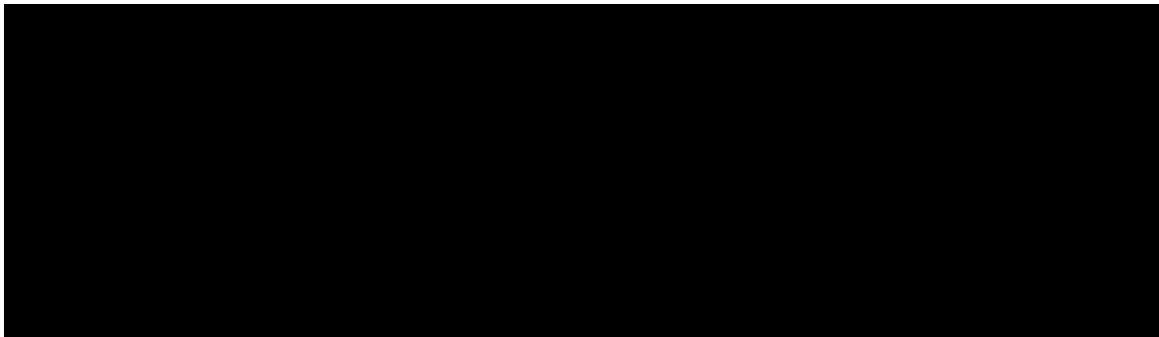
This withdrawal is based on:

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).



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