ARADIGM®

29 October 2019

Chairman of the CHMP
European Medicines Agency (EMA)
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Dear Dr. Enzman,

Subject: Withdrawal of Linhaliq liposomal 135 mg + 54 mg dispersion and solution for modified-release nebuliser dispersion – EMEA/H/C/004394

We would like to inform you that Aradigm Pharmaceuticals Limited has taken the decision to withdraw the application for Marketing Authorisation of Linhaliq liposomal 135 mg + 54 mg dispersion and solution for modified-release nebuliser dispersion. Linhaliq was intended to be used for the prevention and reduction of pulmonary exacerbations in adult patients with non-cystic fibrosis bronchiectasis who have chronic lung infection with *Pseudomonas aeruginosa* and 4 or more exacerbations per year.

This withdrawal is based on the CHMP consideration that the data provided do not allow the committee to conclude on a positive benefit risk balance.

Please note that currently there are no ongoing clinical trials and compassionate use programmes.

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

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

Yours sincerely,

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