TMC PHARMA

31st July 2018

Tomas Salmonson
Läkemedelsverket
Dag Hammarskjölds väg 42
75237 Uppsala
SWEDEN

Subject: Withdrawal of Entolimod TMC, (entolimod), 35 µg/350 µL, solution for injection - Product No. H 0004656

Dear Tomas Salmonson,

I would like to inform you that, at this point of time, TMC Pharma Services Ltd has taken the decision to withdraw the application for Marketing Authorisation of Entolimod TMC, (entolimod), ml35 µg/350 µL, solution for injection, which was intended to be used "to reduce the risk of death following exposure to potentially lethal irradiation occurring as the result of a radiation disaster".

This withdrawal is based on the following reason:

Additional data are required to resolve some of the points raised in the assessment report. Those data were expected to become available during the negotiated response timeline; however, ultimately, generation of those data within the response deadline has proven to not be possible.

As there are no ongoing clinical trials or compassionate use programs, there is no consequence of this withdrawal on such programs.

The US FDA review of the entolimod acute radiation program continues in the absence of such timeframes.

TMC Pharma Services Ltd would like to sincerely thank the (Co) Rapporteurs, EMA, PRAC and CHMP for their time dedicated to reviewing this application and the valuable support and helpful guidance provided during the review process.

We reserve the right to make further submissions at a future date in this or other therapeutic indication(s). I agree for this letter to be published on the EMEA website.

Yours sincerely,