01 June 2017

Dr Tomas Salmonson
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London
E14 4HB United Kingdom

Subject: Withdrawal of Zafiride (NGR-hTNF), 200 micrograms/ml, concentrate for solution for infusion, EMEA/H/C/004455

Dear Dr. Salmonson,

We would like to inform you that, at this point of time, following the day 120 List of Questions and the Clarification Meeting with Rapporteur, Co-Rapporteur and EMA representative, MolMed SpA has taken the decision to withdraw the application for Marketing Authorization of Zafiride (NGR-hTNF), 200 micrograms/ml, concentrate for solution for infusion, which was intended to be used for the treatment of adult patients with advanced malignant pleural mesothelioma who have progressed within six months after a first-line pemetrexed-based therapy.

After discussing, during the said Clarification Meeting, the concerns raised by the review team, as provided in the original day 120 List of Questions, MolMed concluded not to have sufficient time to complete the activities aimed to obtain the data regarding the product manufacturing and control within the assigned CHMP timeframe for this procedure.

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

MolMed believes that Zafiride is a valuable anti-cancer therapy and reserves the right to make further submissions at a future date in this or other therapeutic indications.

The Company confirms that this withdrawal does not affect ongoing clinical trials and compassionate use programs for this product.

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

Yours sincerely,

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