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Dr. Harald Enzmann
European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

09 October 2019

Subject: Withdrawal of Marketing Authorisation Application for NUZYRA, omadacycline, 100 mg powder for concentrate for solution for infusion and 150 mg film-coated tablets, Procedure Number: EMEA/H/C/4715

Dear Dr. Enzmann

I would like to inform you that, at this point in time, the MAA Applicant Paratek Ireland Limited has taken the decision to withdraw the application for Marketing Authorisation for NUZYRA, omadacycline, 100 mg powder for concentrate for solution for infusion and 150 mg film-coated tablets, which was intended to be used for the treatment of adults with community-acquired pneumonia (CAP) or acute bacterial skin and skin structure infections (ABSSSI).

The withdrawal decision was taken for strategic business reasons. This decision is mainly due to the inability of Paratek to secure a partner to support the commercialization of NUZYRA in Europe with only the ABSSSI indication. The insistence for a second CAP study to support approval for this indication in EU has significantly changed the value proposition for NUZYRA in EU and thus all partner discussions have now been discontinued. The inability to find a way forward for this indication will now delay approval for CAP and availability of NUZYRA to patients in Europe by almost 5 years.

Paratek Ireland Limited would like to sincerely thank the Rapporteur, 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. While disappointed in the outcome, primarily for European patients, we remain committed to the ongoing development of omadacycline and intend to resubmit once the second CAP study is complete.

Paratek Ireland Limited confirms that there is no impact for patients in on-going clinical trials or in a compassionate use program.

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

The applicant agrees for this letter to be published on the EMA website.

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Yours sincerely,

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