REMPEX Pharmaceuticals

a wholly-owned subsidiary of ***Melinta Therapeutics, Inc.***

Submission Date: 15 May 2020

Sumathi Nambiar, MD, MPH, Director
Division of Anti-Infective Products
Office of Antimicrobial Products
Food and Drug Administration
Center for Drug Evaluation and Research
5901-B Ammendale Road
Beltsville, MD 20705-1266
Attn: Christopher Smith, PharmD, MPH, BCPS, Regulatory Health Project Manager

Reference: NDA 209776: VABOMERE® (meropenem-vaborbactam): SN 0145
RESPONSE TO PREA NON-COMPLIANCE LETTER

Dear Dr. Nambiar:

Reference is made to IND (b) (6) and NDA 209776 for Vabomere (meropenem-vaborbactam) and the FDA approval letter dated August 29, 2017, which outlined the pediatric postmarketing requirements (PMRs). Reference is also made to the Notification of Non-Compliance with PREA, dated May 1, 2020. Further reference is made to the deferral extension request submitted on April 5, 2020.

The purpose of this submission is to provide a formal response to FDA's Notification of Non-Compliance with PREA letter, dated May 1, 2020 in accordance with the provisions of section 505B(d)(1) of the Federal Food, Drug, and Cosmetic Act [21 U. S. C. 355c(d)(1)].

Vabomere PMR 3248-1 is an open-label, sequential study to assess the pharmacokinetcs (PK), safety, and tolerability of VABOMERE and the PK of meropenem and vaborbactam in children from birth to < 18 years of age with selected serious bacterial infections. Final report submission: March 2020.

Rempex Pharmaceuticals, a wholly owned subsidiary of Melinta Therapeutics, Inc., submitted a deferral extension request for PMR-3248-1 on April 5, 2020 (SN 0141), which includes the current status and the reasons for the delayed pediatric assessment. As outlined in the deferral extension request, the factors attributing to the delay are:

- Challenges consenting and enrolling eligible patients in this PK study with no direct benefit to the subject. To assist with this challenge, the protocol inclusion was amended to expand the entry criteria to allow subjects receiving peri-operative prophylactic antibiotics.

- Multiple reviews of the PK data were required between cohorts to investigate the correct dose for the next cohort. This resulted in delays in enrollment.
- Protocol amendments were subsequently implemented to safely increase the doses being studied, which resulted in the addition of patients/cohorts to be enrolled in the study.

The deferral extension request proposes the submission dates of December 2021 for an Interim CSR Submission (Cohorts 1-4 and 6) and December 2023 for the final CSR Submission (Cohort 5).

We acknowledge that the deferral extension request should have been submitted 90 days prior to March 31, 2020. We also recognize the importance of the PREA program and remains committed to fulfilling the postmarketing requirements under PREA and to the completion of the studies requested by the FDA.

As requested by the FDA a cross-reference letter to this submission will also be submitted to IND 120040.

The enclosed submission is in a fully electronic CTD-format transmitted to the FDA via Electronic Submissions Gateway (ESG). The submission was scanned and found to be virus free using Symantec Endpoint Protection Version 12.1, the latest virus definition (virus pattern file). The main contact person for technical questions is Becky Fontejon, who can be reached at 908-317-1319 (office), 224-377-8030 (fax) or email at bfontejon@melinta.com.

Please contact me at sshangle@melinta.com or 619-300-2961, if you should have any questions.

Sincerely,

{See appended electronic signature page}

Starr Shangle
Senior Director, Regulatory Affairs

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Approval (with eSignature)	Starr Shangle Regulatory 15-May-2020 16:22:55 GMT+0000

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