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November 14, 2024

Jessica Lee, MD
Director, Division of Gastroenterology (DG)
Food and Drug Administration
Center for Drug Evaluation and Research
Document and Records Section
5901-B Ammendale Rd
Beltsville, MD 20705-1266

Response to PREA Non-Compliance Letter

Re: **NDA 209296; SN0142**
CINVANTI® (aprepitant) injectable emulsion, for intravenous use
Response to Pediatric Research Equity Act Non-Compliance Letter for Postmarketing Requirement 3289-2

Attn: Mary Chung, PharmD, Senior Regulatory Project Manager, DRO-II

Dear Dr. Lee:

Reference is made to the New Drug Application (NDA) 209296 for CINVANTI® (aprepitant) injectable emulsion, for intravenous use, approved by the Division on November 9, 2017. Further reference is made to the FDA Notification of Non-compliance with Pediatric Research Equity Act (PREA) letter dated (Reference ID: 5456539) dated October 2, 2024 regarding the pediatric assessment not yet submitted for the following PREA Postmarketing Requirement (PMR):

PMR 3289-2

A study to evaluate pharmacokinetics, safety, and tolerability of a single dose regimen of Cinvanti (aprepitant) injectable emulsion (I.V.) in pediatric patients 0 to 17 years of age undergoing single day highly emetogenic chemotherapy.

Final Protocol Submission:	11/2020
Study/Trial Completion:	04/2024
Final Report Submission:	08/2024

The purpose of this submission is to provide the Division with a Response to Non-compliance Letter including a PREA PMR Deferral Extension Request for PMR 3289-2 (Module 1, Section 1.17.2).

If you have any questions regarding this submission, please contact me at bburgin@herontx.com or by telephone at (919) 599-4135.

Sincerely,

{See appended electronic signature page}

Benjamin M. Burgin, RAC
Executive Director, Regulatory Affairs
Heron Therapeutics, Inc.

This submission was scanned using Symantec Endpoint Protection (version 12.1.6) and is confirmed to be virus free.

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Approval Task	Benjamin Burgin Regulatory 14-Nov-2024 16:15:02 GMT+0000

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