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01 November 2024

Dr. Ann Farrell, MD
Division Director
Center for Drug Evaluation and Research
Office of Cardiology, Hematology, Endocrinology, and Nephrology (OCHEN)
Division of Non-Malignant Hematology (DNH)
Attn: Document Control Room
5901-B Ammendale Road
Beltsville, MD 20705-1266

RESPONSE TO PREA NON-COMPLIANCE LETTER
REQUEST FOR A FULL PEDIATRIC WAIVER

NDA: 205874 - Auryxia® (ferric citrate) Tablets
RE: RESPONSE TO PREA NON-COMPLIANCE LETTER
Request for a full pediatric waiver
Sequence No. 0208

Dear Dr. Farrell:

Reference is made to Keryx Biopharmaceuticals, Inc.'s (Keryx) Supplemental New Drug Application (sNDA) 205874/S-013 for Auryxia® (ferric citrate) tablets approved on 06 November 2017 for the treatment of iron deficiency anemia in adult patients with chronic kidney disease not on dialysis which included the following Post Marketing Requirement (PMR).

PMR 3286-1 Conduct a randomized and controlled study to evaluate the safety and tolerability of Auryxia in pediatric patients (ages greater than or equal to 6 months to less than 18 years) with IDA related to CKD not on dialysis.

Final Protocol Submission: 06/2020 (Submitted)
Study Completion: 05/2024
Final Report Submission: 08/2024

Akebia recognizes the importance of evaluating drugs in the pediatric population and agreed to conduct the following pediatric study to fulfill PMR 3286-1: Study 309 titled, "A 24-Week, Open-Label, Randomized, 2-Arm Study to Evaluate the Safety and Tolerability of KRX-0502 (Ferric Citrate) in Children with Iron Deficiency Anemia Associated with Non-Dialysis Dependent Chronic Kidney Disease (NDD-CKD)."

This submission provides our formal response to the Pediatric Research Equity Act (PREA) Non-Compliance Letter dated 20 September 2024. Akebia has engaged in diligent efforts to initiate Study 309 but has faced substantial challenges as the company has discussed with the review division over the last several years and filed a deferral extension request that was denied on 05 April 2024 (communications between Keryx and the Division regarding PMR

3286-1 are provided in the waiver request). Subsequently, Akebia has determined that Study 309 is highly impracticable or impossible and would not meaningfully benefit or be used by pediatric patients. For these reasons, Akebia respectfully requests a waiver from PMR 3286-1 (Module 1.17.2) in accordance with Section 505B(a)(5)(A)(i) and (iii) of the Federal Food, Drug, and Cosmetic Act.

If you have any questions or comments regarding this submission, please do not hesitate to contact me at gjoshi@akebia.com or 781-354-6694.

Sincerely,

Gunjita Joshi

Digitally signed by Gunjita Joshi
Reason: I am approving this document
Date: 2024.10.29 12:39:26 -04'00'

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