NDA 212728/S-014

SUPPLEMENT APPROVAL

Biohaven Pharmaceuticals, Inc.
U.S. Agent for Biohaven Pharmaceutical Ireland Designated Activity Company
Attention: Marianne Frost
Senior Vice President, Regulatory Affairs
215 Church Street
New Haven, CT 06510

Dear Ms. Frost:

Please refer to your Supplemental New Drug Application (sNDA) dated and received October 13, 2021, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Nurtec ODT (rimegepant) Orally Disintegrating Tablets.

We also refer to our approval letter dated March 31, 2022, which contained the following error: This "Changes Being Effected in 30 days" supplemental new drug application provides for the addition of (b) (4)

This replacement approval letter incorporates the correction of the error. The effective approval date will remain March 31, 2022, the date of the original approval letter.

This "Changes Being Effected in 30 days" supplemental new drug application provides for the addition of (b) (4) as an alternate drug substance manufacturer.

APPROVAL

We have completed our review of this supplemental application. This supplement is approved.

We remind you that you must comply with reporting requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Avani Patel, Regulatory Business Process Manager, at (240) 402 - 1845.

Sincerely,

{See appended electronic signature page}

Gurpreet Gill-Sangha, Ph.D.
Branch Chief, Branch 3
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Gurpreet
Gill Sangha

Digitally signed by Gurpreet Gill Sangha
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