CERTARA®
Accerlating Medicines, Together

CASE STUDY

To View Online: www.certara.com/case-study/biohaven/

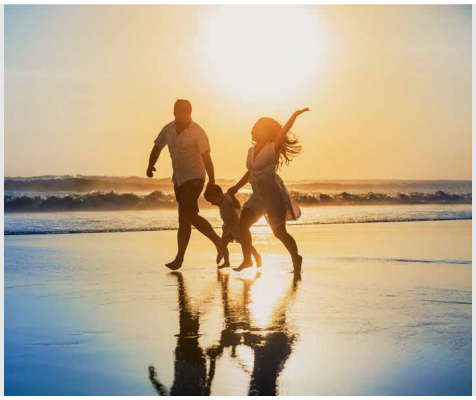
BIOHAVEN ACHIEVES FDA APPROVAL WITH NURTEC™

biohaven pharmaceuticals

In February 2020, Biohaven announced that the U.S. Food and Drug Administration (FDA) approved Nurtec™ ODT (rimegepant) for the acute treatment of migraines in adults. It is the first and only calcitonin gene-related peptide (CGRP) receptor antagonist available in a fast-acting, orally disintegrating tablet (ODT).

In 2017, Biohaven was in need of clinical pharmacology and pharmacometrics expertise for Nurtec to supplement their drug development team. They engaged with Certara because of our proven experience in clinical pharmacology and pharmacometrics.

Certara was able to fill the gaps and worked closely alongside Biohaven's scientists to use quantitative methods to advance Nurtec's path to approval.



"Certara's contribution to the drug development program for Nurtec ODT was substantial. Their clinical pharmacology representative worked seamlessly with the Biohaven Development Team. Certara's considerable expertise in clinical pharmacology and pharmacometrics and flawless execution supported Nurtec's clinical development team and helped to prepare the clinical pharmacology NDA components."

Richard Bertz, PhD
Vice President
Clinical Pharmacology & Pharmacometrics

Migraine headaches are a debilitating neurological disorder that affects approximately 15% of the adult population in the United States (US), comprising approximately 38 million adults. Migraines rank as the third most prevalent disease worldwide and the seventh highest specific cause of disability worldwide.

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