

FDA Grants Orphan Drug Designation to NovelWise's NBM-BMX for Uveal Melanoma

NovelWise received FDA Orphan Drug Designation for NBM-BMX, its selective HDAC8 inhibitor for uveal melanoma, strengthening momentum after Fast Track status.

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[EINPresswire.com/](https://www.einpresswire.com/) -- [NovelWise Pharmaceutical](#) Corporation

announced that the U.S. Food and Drug Administration (FDA) has granted [Orphan Drug Designation](#) (ODD) to its selective HDAC8 inhibitor, [NBM-BMX](#), for the treatment of uveal melanoma (UM).

This designation follows the recent Fast Track status and further accelerates the development of NBM-BMX.

NBM-BMX is a next-generation HDAC8-selective inhibitor designed to modulate tumor DNA repair and survival pathways, with the potential to improve clinical outcomes in patients with this aggressive rare cancer.

Key Benefits of Orphan Drug Designation

- 7 years of U.S. market exclusivity upon approval (independent of patents)
- Waiver of FDA PDUFA filing fee (approximately USD 4.4M in 2025)
- 25% federal tax credit on U.S. clinical trial expenses
- Enhanced FDA regulatory guidance and more frequent scientific interactions
- Eligibility for Accelerated Approval and Rolling Review, strengthened by existing Fast Track status



FDA Grants Orphan Drug Designation to NovelWise's NBM-BMX, Adding to Its Fast Track Advancement in Uveal Melanoma

Advancing Clinical Development Across the United States

NovelWise is conducting its ongoing clinical program in collaboration with ten leading cancer centers across the U.S.

Three sites have completed Site Initiation Visits (SIVs), and the study is progressing toward expanded activation and enrollment.

John Soong, MD, Chief Executive Officer of NovelWise, commented:

“Receiving both Fast Track Designation and now Orphan Drug Designation underscores NBM-BMX’s promise in addressing a high unmet medical need for patients with uveal melanoma. These regulatory milestones will accelerate the development pathway for NBM-BMX and support our mission of delivering innovative therapy options to patients suffering from rare and aggressive cancers.”

Market Opportunity

According to Smart Insights Market Research (April 2025), the global uveal melanoma treatment market was valued at USD 650 million in 2022 and is projected to reach USD 1.25 billion by 2030, representing a compound annual growth rate (CAGR) of 8.5%.

About NovelWise Pharmaceutical Corporation

NovelWise Pharmaceutical Corporation is a biotechnology company focused on developing first-in-class and best-in-class epigenetic and oncology therapeutics, with a strategic emphasis on rare cancers and BAP1-mutation-driven tumors.

The company’s lead asset, NBM-BMX, is a selective HDAC8 inhibitor currently in clinical development for uveal melanoma and additional solid tumors characterized by BAP1 loss or dysregulation.

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