

NovelWise Pharma Announces First Patient Dosed in Phase I/II Trial of NBM-BMX for Metastatic Uveal Melanoma

NovelWise announces first patient dosed in its Phase I/II trial of NBM-BMX for metastatic uveal melanoma, following FDA Fast Track and Orphan Drug designations

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This first patient dosing milestone supports the ongoing clinical evaluation of NBM-BMX as an investigational agent in metastatic uveal melanoma.”

John Soong

Pharmaceutical Corporation, a clinical-stage biopharmaceutical company developing first-in-class therapeutics for difficult-to-treat cancers, today announced that the first patient has been dosed in its Phase I/II clinical trial evaluating [NBM-BMX](#), a selective HDAC8 inhibitor, for the treatment of [metastatic uveal melanoma](#) (mUM). The U.S. Food and Drug Administration (FDA) has granted both Fast Track Designation and [Orphan Drug Designation](#) for NBM-BMX in Metastatic Uveal Melanoma.

The Fast Track Designation acknowledges the potential of

NBM-BMX to address a serious and life-threatening condition with significant unmet medical need. It also reflects the FDA's recognition of the strong preclinical data supporting HDAC8 inhibition in uveal melanoma biology, as well as NBM-BMX's potential to deliver meaningful clinical benefit. Fast Track status provides important advantages, including more frequent FDA interactions, eligibility for rolling review, and the potential for expedited development and regulatory pathways.

In addition, Orphan Drug Designation (ODD) provides several regulatory and commercial incentives, including:

- 7 years of U.S. market exclusivity upon approval
- Tax credits for clinical trial expenses
- Waiver of FDA application fees
- Eligibility for Orphan Grants Program support

The first patient has now been treated in NBM-BMX-004, a multi-center, open-label Phase I/II trial assessing safety, pharmacokinetics, and preliminary anti-tumor activity in metastatic uveal melanoma (ClinicalTrials.gov ID: NCT07136181). The Phase I portion evaluates safety and

tolerability. Pending successful safety review, the study will transition directly into a Phase II expansion cohort, designed to evaluate objective response rate (ORR) and progression-free survival (PFS).

“Dosing the first patient in this important study represents a major milestone for NovelWise and for patients living with metastatic uveal melanoma,” said John Soong, MD., CEO of NovelWise Pharmaceutical Corporation. “Receiving both Fast Track and Orphan Drug Designations underscores the FDA’s recognition of the strong mechanistic rationale, preclinical efficacy signals, and the urgent need for new therapeutic options in this aggressive cancer. We believe NBM-BMX has the potential to transform treatment expectations for patients with this devastating disease.”

Metastatic uveal melanoma is a rare but highly aggressive malignancy, with approximately half of all patients with primary uveal melanoma developing metastatic disease, most commonly to the liver. There are currently no systemic therapies proven to improve overall survival in the metastatic setting.

About NBM-BMX

NBM-BMX is a next-generation, orally administered small-molecule inhibitor of histone deacetylase 8 (HDAC8). HDAC8 plays a key role in epigenetic dysregulation, tumor proliferation, DNA damage repair, and immune suppression. NBM-BMX has demonstrated potent and selective HDAC8 inhibition across multiple preclinical cancer models and has completed Phase I monotherapy studies in advanced solid tumors. It is also being evaluated in a Phase I/II study in newly diagnosed glioblastoma in combination with temozolomide.

About NovelWise Pharmaceutical Corporation

NovelWise Pharmaceutical Corporation is a clinical-stage biotechnology company developing mechanism-driven oncology therapies based on selective HDAC8 inhibition and epigenetic modulation. Headquartered in Taipei, Taiwan with global operations in San Diego, California, NovelWise is committed to delivering innovative medicines for cancers with urgent unmet needs.

Forward-Looking Statements

This press release contains forward-looking statements relating to the development and clinical potential of NBM-BMX. These statements involve risks and uncertainties, including clinical trial outcomes, regulatory interactions, and manufacturing factors. NovelWise undertakes no obligation to update any forward-looking statements.

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