NovelWise Pharmaceutical Receives FDA Fast Track Designation for NBM-BMX in Metastatic Uveal Melanoma

Fast Track designation underscores NovelWise's clinical momentum and the potential of NBM-BMX as a first-in-class HDAC8 inhibitor for metastatic uveal melanoma

SAN DIEGO, CA, UNITED STATES, October 16, 2025 /EINPresswire.com/ -- Designation supported by robust preclinical data in uveal melanoma and clinical data from prior Phase I studies of NBM-BMX; expedites path for a first-in-class selective HDAC8 inhibitor

Novelwise Pharmaceutical is a biopharmaceutical company dedicated to the discovery and development of a series of histone deacetylase (HDAC) inhibitor programs for oncology and other diseases with high unmet medical needs

San Diego, Calif. — October 14, 2025 — NovelWise Pharmaceutical Corporation USA ("NovelWise") today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for NBM-BMX, a selective HDAC8 inhibitor, for the treatment of metastatic uveal melanoma (mUM).

The FDA granted the designation based on its review of NovelWise's robust preclinical data in uveal melanoma models together with clinical data from prior Phase I studies of NBM-BMX. Fast Track is designed to facilitate development and expedite review of investigational medicines intended to treat serious conditions with unmet medical need, offering early and frequent FDA interactions, rolling review, and potential eligibility for Priority Review if criteria are met.

"Fast Track status is a meaningful accelerator for NBM-BMX and a strong signal of the program's potential," said John Soong, MD, Chief Executive Officer of NovelWise. "The FDA's

decision—supported by our preclinical data in uveal melanoma and our completed Phase I experience—allows us to move faster and smarter with regulators as we advance toward patients who urgently need better options."

Clinical Development Next Steps
NovelWise will initiate site initiation visits in late October and open enrollment in a Phase Ib/II study in early November 2025 evaluating NBM-BMX as a single agent in mUM. The study will assess safety, pharmacokinetics, and signals of antitumor activity. Details will be posted to ClinicalTrials.gov prior to first-patient-in.

Building on Prior Clinical Experience
NBM-BMX has an established clinical foundation from completed Phase I trials, which informed dose selection, safety monitoring, and scheduling for the upcoming mUM study. In parallel, NBM-BMX is being investigated in an ongoing Phase Ib/II glioblastoma (GBM) program in combination with temozolomide (TMZ). Learnings from that program will further refine development in mUM.

About NBM-BMX
NBM-BMX is a next-generation, selective histone deacetylase 8 (HDAC8) inhibitor designed to modulate epigenetic drivers in solid tumors. NBM-BMX is investigational and has not been approved by the FDA or any regulatory authority.

About Metastatic Uveal Melanoma
Uveal melanoma is the most common primary intraocular malignancy in adults. Patients who progress to metastatic disease—most often to the liver—face poor outcomes and limited treatment options, underscoring the need for novel mechanisms and expedited development pathways.

About NovelWise Pharmaceutical
NovelWise Pharmaceutical Corporation USA is a clinical-stage biotechnology company developing precision small-molecule medicines in oncology. The company's lead program, NBM-BMX (HDAC8 inhibitor), is in clinical development across multiple indications, including metastatic uveal melanoma and glioblastoma. For more information, please contact NWP-US-info.tw@novelwisepharma.com.

Forward-Looking Statements
This press release contains forward-looking statements, including statements regarding the timing of clinical trial initiation, site activation and enrollment, the potential benefits of FDA Fast Track designation, and the therapeutic potential of NBM-BMX. These statements involve risks and uncertainties that could cause actual results to differ materially, including risks related to clinical trial execution, regulatory interactions and outcomes, manufacturing, and competitive developments. NovelWise undertakes no obligation to update forward-looking statements, except as required by law.

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