Expanded Access to NovelWise Pharmaceutical Corporation

Investigational Medicines

Expanded Access Policy

At NovelWise Pharmaceutical Corporation, we are committed to discovering and developing innovative therapies that have the potential to fundamentally improve the way patients with metastatic uveal melanoma are treated. This Expanded Access Policy applies to NBM-BMX, a selective HDAC8 inhibitor currently under investigation for the treatment of metastatic uveal melanoma (mUM) in the United States. This policy is developed in accordance with U.S. Food and Drug Administration (FDA) regulations governing Expanded Access programs.

Policy Purpose and Scope

The purpose of this policy is to outline the conditions under which NovelWise Pharmaceutical Corporation may provide expanded access (also known as compassionate use) to its investigational medicine, NBM-BMX, for eligible patients in the U.S. Expanded Access is not a substitute for participation in a clinical trial but may be considered when certain criteria are met.

Eligibility Criteria for Patients

To be eligible for Expanded Access consideration, patients must meet the following conditions:

- Suffer from a serious or life-threatening condition (metastatic uveal melanoma).
- Have received appropriate standard treatments without success, and no comparable or satisfactory alternative therapy is available.
- Are ineligible for participation in an ongoing clinical study of NBM-BMX, including due to geographic or eligibility limitations.
- Reside in the United States and are under the care of a qualified treating physician.

Responsibilities of the Treating Physician

Requests for Expanded Access must be submitted by a qualified treating physician who:

- Is appropriately licensed and authorized to administer investigational drugs in the United States; and
- Agrees in writing to comply with all applicable FDA and local regulations governing Expanded Access; and
- Obtains Institutional Review Board (IRB) approval and patient informed consent prior to treatment; and
- Agrees to comply with NovelWise Pharmaceutical Corporation's requirements regarding medical criteria, safety reporting, drug handling and accountability, ongoing data collection, and protection of intellectual property.
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Request Submission and Review Process

Treating physicians seeking Expanded Access for their patients should submit a written request to:

expandedaccess@novelwisepharma.com

NovelWise Pharmaceutical Corporation will make its best effort to acknowledge receipt of each request within five (5) business days. All requests will be reviewed by the company's medical and regulatory teams to assess eligibility, medical justification, and product availability.

Decision and Conditions of Access

NovelWise reserves the right to approve or deny any Expanded Access request at its sole discretion. Approval decisions will be based on medical rationale, available safety data, regulatory requirements, and drug supply considerations. Access may be discontinued if new safety findings arise, the clinical trial completes, or the product becomes commercially available.

Policy Revision and Transparency

NovelWise Pharmaceutical Corporation may revise this policy at any time to reflect updated regulatory guidance, internal governance, or product development status. Any modifications will be publicly posted on this webpage upon implementation.