Managed Access Program Policy

Introduction

Biomed Valley Discoveries Inc. (BVD) is a clinical-stage biotechnology company on a quest to make a meaningful difference for patients. While many companies are constrained when evaluating managed access programs, with a "return on investment" lens, we welcome these programs because of our dedication to providing Hope for Life.

At BVD, we are passionate about supporting patients' medical needs and to do that, BVD has developed a Managed Access Program Policy. A Managed Access Program may also be referred to as "pre-approval access", "expanded access", "compassionate use", "right to try" or "named patient basis programs", as defined by applicable regulations. This policy outlines how BVD evaluates and responds to requests for access to our investigational product(s).

Scope

This policy is applicable to requests on behalf of individual patients.

Policy

With an appropriate sense of urgency, and in accordance with all applicable regulatory requirements, BVD will work with qualified healthcare providers to make our investigational products available to their patients.

The primary option for patients to access the investigational products is to participate in a clinical trial. Patients and their healthcare providers are advised to visit https://biomed-valley.com/ to learn more about current and planned clinical trials. Information regarding the current ulixertinib Expanded Access Program can be accessed here: https://clinicaltrials.gov/study/NCT04566393.

We, at BVD, understand that there are exceptional circumstances where access to investigational products outside of a clinical trial is warranted. Under our policy, a treating healthcare provider may submit requests for managed access to BVD. While this policy outlines the general criteria to be used by BVD in evaluating a request and should be considered by the provider before submitting a request, each case is unique and BVD may supplement the general criteria with additional, specific criteria and requirements at its discretion.

Patient Eligibility Criteria:

- *The patient has been diagnosed with a serious or immediately life-threatening disease or condition.*
- *The patient has undergone appropriate standard treatments without success and no comparable or satisfactory alternative treatment is available or exists to treat the disease or condition.*

- *The patient is ineligible or unable to participate in any ongoing clinical study of the investigational product, including lack of access due to geographic limitations.*
- *The patient has a disease or condition for which there is sufficient evidence of a potential benefit from the use of the investigational product and the benefit outweighs the known or anticipated risks.*

Additional Criteria:

- *The provision of the investigational product will not interfere with or compromise the clinical development of the product.*
- *There must be a sufficient amount of the investigational product available for the requested use, ensuring that an adequate supply exists for ongoing and planned clinical trials and other supporting work required for regulatory submissions.*
- *BVD may request samples from the healthcare provider/patient that may benefit the development of the investigational product.*

Treating Healthcare Provider Criteria:

- *The healthcare provider(s) attending to the patient(s) who is/are receiving an investigational product through a Managed Access Program is (are) properly licensed and fully qualified to administer the product. The healthcare provider must agree in writing to comply with:*
  - Any applicable country-specific legal and regulatory requirements related to providing an investigational product under a Managed Access Program.
  - Any BVD requirements in terms of medical criteria, safety reporting, drug supply/use, and protection of intellectual property.

How to Submit a Request

A treating healthcare provider may submit requests to BVD via the "Scientific Collaboration / Drug Request Contact Form" on our website: https://biomed-valley.com/contact-us/.

Acknowledgment by BVD of receipt of the request is anticipated to occur within 5 business days. The posting of this policy by BVD shall not serve as a guarantee of access to any specific investigational drug by any individual patient.

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