# SYROS PHARMACEUTICALS, INC. POLICY ON ACCESS TO INVESTIGATIONAL PRODUCTS OUTSIDE OF A CLINICAL TRIAL

## 1. Purpose

The purpose of this policy is to describe the guidelines by which Syros Pharmaceuticals, Inc. ("**Syros**") will consider requests for access to one of its investigational products outside of a clinical trial.

#### 2. Policy

Syros' development resources are focused on conducting clinical studies required by regulatory authorities to assess the safety and effectiveness of its investigational products in specific disease indications, and to seek and obtain marketing approval of its investigational products. Syros will consider making its investigational products available to seriously ill patients who have exhausted other treatment options based on the criteria set forth in this policy. Any such request must be made in writing by a qualified physician and be delivered to the following e-mail address: expandedaccess@syros.com. Syros will endeavor to acknowledge receipt of such request within ten (10) business days. In assessing whether to make an investigational product available, Syros will consider, among other things, the criteria set forth below. Even if the criteria set forth below are satisfied, however, Syros may elect in its sole discretion not to make an investigational product available outside of a clinical trial and Syros may discontinue such availability at any time. The Chief Medical Officer (or his/her designee) will maintain records documenting each request for access to an investigational product outside of a clinical trial and the final disposition of such request.

### 3. <u>Criteria for Consideration of Requests for Use of an Investigational Product</u>

### 3.1 Patient Eligibility Criteria.

To be eligible for access to an investigational product outside of a clinical trial, patients must meet the following criteria:

- 3.1.1 the patient must suffer from a serious or immediately life-threatening disease or condition:
- 3.1.2 the patient must have undergone appropriate standard treatments without success and no satisfactory alternative, including a clinical trial of another investigational agent, is available to treat the disease or condition;
- 3.1.3 the patient is ineligible for participation in any ongoing clinical study of the Syros investigational product;
- 3.1.4 the patient meets any other pertinent medical criteria for access to the investigational product as the Chief Medical Officer may determine in his/her sole discretion; and
- 3.1.5 the patient and his/her treating physician are located in a jurisdiction in which (a) Syros has development and commercialization rights for the investigational product and (b) the investigational product can be provided and used under applicable legal and regulatory requirements.

## 3.2 <u>Investigational Product Criteria</u>.

The investigational product that is the subject of request must meet the following criteria:

- 3.2.1 the investigational product is under investigation in one or more clinical studies;
- 3.2.2 there is sufficient evidence to expect that the investigational product will have an acceptable safety profile and be efficacious for the disease or condition for which it is intended to be used:
- 3.2.3 the provision of the investigational product will not interfere with or compromise the clinical development or pathway to regulatory approval thereof; and
  - 3.2.4 there is adequate supply of the investigational product.

#### 4. <u>Treating Physician Criteria and Responsibilities</u>.

The physician(s) attending to a patient receiving an investigational product under this policy must be properly licensed and fully qualified to administer the investigational product to the patient. In addition, such physician must: (a) obtain any approvals from applicable investigational review boards/ethics committees and satisfy any other applicable country-specific legal and regulatory requirements related to providing an investigational product outside of a clinical trial; and (b) agree in writing to comply with any Syros requirements in terms of medical criteria, safety reporting, drug supply/use, protection of intellectual property, and conversion to participation in a Syros-sponsored clinical trial or access to commercially available product if approved for the patient's disease or condition.

### 5. <u>Additional Information</u>.

Information about completed and ongoing clinical trials of Syros' investigational products can be found at <a href="https://www.clinicaltrials.gov">www.clinicaltrials.gov</a>.

Adopted January 9, 2017