

## ATOSSA THERAPEUTICS' EXPANDED ACCESS POLICY

### PURPOSE AND PHILOSOPHY

Atossa Genetics is a clinical-stage biopharmaceutical company developing novel, proprietary therapeutics and delivery methods for breast cancer and other breast conditions.

Atossa Genetics' development resources are focused on conducting clinical studies to fully answer important scientific questions about the potential risks and benefits of the investigational products, and to obtain marketing approval by the FDA and other regulatory health authorities.

Atossa Genetics is committed to making investigational products available to seriously ill patients who have exhausted other treatment options. A treating physician, who is able to comply with the requirements that are stated in this document, may request information about how to apply for access to Atossa Genetics' investigational products by contacting the Company.

The purpose of this policy is to describe the requirements for Expanded Access to Atossa Genetics investigational products to patients outside of a clinical study.

### ATOSSA GENETICS' APPROACH TO REQUESTS FOR ACCESS TO EXPERIMENTAL THERAPIES

- Participation in clinical trials is the first and most preferable route.
- If participation in clinical trials is not an option, physicians may consider other options, which may include expanded access programs managed by the company or single-patient expanded access.
- Requests are considered on a case-by-case basis in a fair and equitable manner.

### GENERAL CRITERIA USED TO EVALUATE ACCESS REQUESTS FOR INDIVIDUAL PATIENTS

The patient has a serious or life-threatening condition with no satisfactory alternative.

- Assessment that benefits outweigh the risks to the patient.
- Assessment that the company has an adequate supply of the investigational medicine.
- A determination that expanded access will not interfere with the company's ability to complete clinical trials in a timely fashion or which might otherwise delay marketing approval and ultimately availability to all patients.

### CURRENTLY AVAILABLE INVESTIGATIONAL THERAPIES

Oral endoxifen (for pre-surgical and adjuvant treatment of Luminal A ER+ breast cancer; mammographic breast density).

### HOW TO APPLY

Interest in the Expanded Access program must be provided to Atossa Genetics by a medically qualified physician, using the Expanded Access Request form ([www.atossagenetics.com/clinical-trials/#ea-form](http://www.atossagenetics.com/clinical-trials/#ea-form)) on the Atossa Genetics website ([www.atossagenetics.com](http://www.atossagenetics.com)).

- Atossa Genetics may request additional information, including patient history, in order to fully evaluate the request.
- If the physician will be the sponsor for the IND, he or she is required to obtain necessary ethical and regulatory clearances, including informed consent, as well as provide reporting on treatment outcomes. Atossa Genetics may be able to provide some assistance in these endeavors.

Requests for Expanded Access will be acknowledged within 5 working days.

CONTACT INFORMATION

For fastest consideration, please use the Expanded Access Contact form at [www.atossagenetics.com](http://www.atossagenetics.com).

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