SeattleGenetics®

ABOUT ACCESS TO INVESTIGATIONAL PRODUCTS

Effective June 2017

At Seattle Genetics, we serve patients by developing innovative medicines to improve the lives of people with cancer. We focus on making approved medicines available to the patients who need them. In addition, through clinical trials, we help patients with unmet medical needs access our investigational products that are not yet approved.

Clinical trials are research studies that involve volunteers and are designed to determine the safety and efficacy of potential new medicines. Before new treatments can be made publicly available, the U.S. Food and Drug Administration (FDA) and other health authorities around the world require that they are studied in clinical trials. We conduct a wide range of trials in a number of diseases including Hodgkin lymphoma, non-Hodgkin lymphoma, acute myeloid leukemia and other blood cancers, and urothelial cancer and other solid tumors.

In some cases, patients or their physicians may believe that a patient with a serious or immediately life-threatening disease could benefit from an investigational product, but the patient does not qualify for an ongoing clinical trial. In rare circumstances and as permitted by applicable law, these patients may be able to receive investigational products from Seattle Genetics outside the clinical trial through a practice often called "compassionate use" or "expanded access." We base all decisions about compassionate use solely on clinical evidence, and these decisions are guided by certain criteria that are generally accepted by the pharmaceutical and biotechnology industry.

Process for Requesting Expanded Access

If you are a patient with questions regarding early access to an investigational product, you should consult with the physician who is treating your cancer. Any request for access to an unapproved product being investigated by Seattle Genetics should come from your physician through an email request to the head of our Medical Affairs department medinfo@seagen.com. We evaluate each request with the highest priority and have made a commitment to respond within 48 hours.

Seattle Genetics is working as fast as possible to safely develop our investigational products so that we can best help cancer patients. We appreciate the invaluable contributions of patients and medical professionals in support of the research process.

Criteria Used for Considering Requests for Expanded Access

The following general criteria guide our decisions regarding access to investigational products:

- Patient must have a serious and immediately life-threatening illness.
- Patient must have exhausted all other available effective treatments approved for his or her condition and is no longer responsive to or able to tolerate these treatments.
- Patient **must not** be eligible to enroll in ongoing relevant clinical trials involving the investigational product.
- Patient must have a disease that is similar in type and stage to the indication(s) for which the investigational product is currently being studied and for which there is sufficient evidence to expect that the patient may derive a clinically meaningful benefit.
- Patient is willing and able to provide informed consent to use the investigational product.
- Seattle Genetics has adequate supply of the investigational product.
- Expanded access will not interfere with the development of the investigational product or slow the company's ability to broadly deliver the therapy to patients.

Helpful Resources

- Learn about the FDA's position on compassionate use
- Find out more about Seattle Genetics clinical trials
- Search open clinical trials at ClinicalTrials.gov to find out if a clinical trial exists for a specific medicine or particular disease