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Pre-Approval Access of Leronlimab at CytoDyn Outside a Clinical Trial

CytoDyn's purpose is to improve patients' quality of life through therapeutic innovation. To this end, CytoDyn is committed to providing access to leronlimab for eligible patients with serious unmet medical needs.

This Statement outlines CytoDyn's position on providing leronlimab, a drug that has not received regulatory approval by the FDA, to patients outside the clinical trial setting.

Principles for Pre-Approval Access Requests

At CytoDyn, our core values of integrity, responsibility, and service guide our decision-making. We adhere to these values, and we strive to maintain the highest ethical standards in our clinical development programs. We also comply with regulatory and industry guidelines as we seek to make advances in oncology and other indications. Our goal is to support patients and healthcare providers (HCP) responsibly and transparently while prioritizing patient safety and the integrity of our clinical development program.

The main pathway for gaining access to leronlimab is for a patient to enroll in an active clinical trial. To view a list of open clinical trial(s) at certain points in time, visit www.clinicaltrials.gov. For patients who cannot enroll in clinical trials, pre-approval access may be considered.

Patients can access leronlimab outside the clinical trial setting through an emergency IND (eIND) for eligible patients with solid tumors. The patient must have a serious or immediately life-threatening disease or condition and have no comparable or satisfactory alternative therapy options available.

Our policy for considering pre-approval access to leronlimab is grounded in key ethical principles, including that:

- All requests for pre-approval access are considered in a fair and just manner
- There is sufficient understanding of the potential benefits and risks of the investigational medicine
- Patients are not put at risk of unnecessary harm
- Fulfillment of pre-approval access will not jeopardize leronlimab's development program that may lead to broader public access through marketing authorization
- Fulfillment of pre-approval access fully complies with applicable laws and regulations

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Criteria to Pre-Approval Access of Leronlimab Outside a Clinical Trial

Whenever possible, use of leronlimab by a patient as part of a clinical trial is preferable because clinical trials generate data regarding efficacy and safety. However, when requested, CytoDyn will consider providing leronlimab under the following circumstances:

- The patient:
  - Has a serious or life-threatening disease or condition
  - Is not eligible or able to participate in a clinical trial
  - Has an unmet need or no comparable or satisfactory alternative treatment options currently available
- The patient's HCP
  - Evaluates the benefits and risks of participating in an eIND
  - Directly requests access to an eIND
  - Is willing to submit the eIND application to the FDA

Contact

For HCPs seeking to gain access to leronlimab for their patients, please contact the below:

- For an eIND: dai@cytodyn.com

The posting of this Statement does not serve as a guarantee of access to leronlimab by any HCP or patient.

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