	Policy		
cullinan ONCOLOGY	Compassionate Use	**Document Number:**	POL-CLN-001
		Version:	1.0

Cullinan Oncology Inc. (Cullinan) is a biopharmaceutical company focused on developing a diversified pipeline of targeted oncology and immuno-oncology therapies with transformative potential for cancer patients.

Access to Investigational medicines intended to treat serious diseases for individual patients is also known as “compassionate use.” We recognize that not all patients may be eligible or able to enroll in a clinical trial. We support access to investigational drugs for people with life-threatening disease and those who meet specific requirements. Whenever possible however use of the investigational agent as part of a clinical trial is the preferred route for access.

A single request for compassionate use of an investigational medicine, can only be considered if all of the following conditions are met:

i. The disease or condition being studied is life-threatening.
ii. There are no adequate alternative therapies or clinical trials available.
iii. Sufficient preliminary efficacy and safety data exist for the drug and/or drug delivery device in order for Cullinan to make a benefit-risk analysis consistent with the establishment of a compassionate use program.
iv. Sufficient clinical data are available to identify an appropriate dose.
v. A patient’s treating physician and Cullinan’s Chief Medical Officer both believe there is the potential for the specific patient under consideration to reasonably expect benefit from the treatment, and there is robust evidence to support the possibility that the patient will benefit.
vi. Adequate drug supply can be assured to support both the ongoing clinical trials and approved compassionate use, until product becomes commercially available.
vii. The patient is not eligible or a candidate for one of the Cullinan-sponsored studies on the therapy. Geographic limitations to participation in a trial is not a criterion for ineligibility.
viii. Compassionate access will not adversely impact the clinical development program, in particular, the conduct of a pivotal clinical trial that is required for regulatory approval.
ix. The request is made by the patient’s treating physician, unsolicited by Cullinan or any other individual or organization. This request will provide evidence that the patient will have continual access to the level of medical supervision appropriate to safeguard the patient while being exposed to an experimental therapy.

Requests must include the following information:

1. Date of the request
2. The requesting physician’s contact information and qualifications

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3. Name of the requested investigational product, the treatment plan and expected treatment duration
4. Medical reason why use of the investigational agent is in the patient's best interest
5. Justification for why the patient is not eligible for an open clinical trial

A response will be provided within 30 days. Potential responses include an approval, request for additional information or a rationale for non-approval.

Any pre-approval access to an investigational product must always comply with the applicable country-specific laws and regulations, including medicine importation requirements, and approvals from applicable regulatory bodies and by an Institutional Review Board or Ethics Committee from the treating hospital must be secured. If approved, the patient (or his or her guardian) must provide informed consent and consent to comply with the safety and monitoring requirements defined by Cullinan. The treating physician must also agree to comply with the safety and monitoring requirements. Compassionate use will cease to be made available if data from ongoing clinical trials does not demonstrate a positive risk/benefit to patients. For patients that meet Cullinan's criteria, treating physicians can make a request via compassionateuse@cullinanoncology.com.