CellCentric's Expanded Access Policy for inobrodib (CCS1477)

CellCentric is dedicated to improving the lives of people with cancer.

Our mission is to transform the outcomes and quality of life for people living with some of the most difficult to treat and under-addressed cancer types. We are focused on conducting the clinical trials necessary to gain regulatory approvals to make inobrodib broadly available to patients as quickly as possible. We are privileged to collaborate with the clinical investigators and to have the patients participate as they do.

We also understand that there are seriously ill patients who will not be eligible for our clinical trials and may not have options for alternative therapies, including investigational therapies in trials being conducted by other sponsors. In these circumstances, CellCentric will consider providing a requesting physician with pre-approval access to inobrodib for the treatment of an individual patient outside a clinical trial, provided certain conditions are met. These conditions include, but are not limited to, the following:

- The patient has a serious or life-threatening cancer and is either no longer responsive to, or no longer able to, tolerate any available treatment option
- There is a scientific rationale for considering the use of inobrodib in the patient's type of cancer
- There is sufficient data available to determine an appropriate dose and schedule for the patient
- A benefit-risk analysis, based on both the available clinical data as well as the requesting physician's assessment of the patient's condition and history, supports making inobrodib available
- Making inobrodib available will not negatively impact or delay the conduct of clinical trials, or regulatory reviews or approvals, of inobrodib for broader patient access
- Adequate supply of inobrodib is available for the anticipated duration of the patient's treatment

Submitting the request

All requests must be submitted by the patient's treating physician; regrettably we cannot accept requests directly from patients or their representatives.

The requesting physician must agree to obtain appropriate regulatory and ethics committee approvals and comply with all regulatory obligations. This includes obtaining patient consent as appropriate, monitoring the patient, managing investigational product, and safety reporting.

Physicians should submit their requests to **clinical@cellcentric.com**. We regularly monitor this mailbox and will try to acknowledge each submitted request within 3 business days of receipt.

Evaluating the request

CellCentric is committed to evaluating all requests on a case by case basis and in a fair and equitable manner. Note that patients' circumstances and/or medical histories differ, therefore the fact that inobrodib may have been made available for the treatment of one particular patient does not mean it will be made available to another.