In order to comply with regulatory requirements, Amgen n.v. needs to obtain the following information before being able to process your request for drug supply in the Compassionate Use Program with blinatumomab in adult MRD+ B-precursor ALL.

**May we kindly request you to send the next pages accurately completed and signed to EU\_BE\_blinatumomab@amgen.com together with:**

1. **Short medical history of patient (e.g. last consultation report) (anonymized)**
2. **Results of MRD testing (anonymized)**

Physician Declaration Form

In order to comply with the Compassionate Use program with blinatumomab in adult MRD+ B-precursor ALL*,* the undersigned physician declares that

* + He/she is personally responsible for the use of a medicinal product that is not yet authorised. He/she accepts the risk of treating his/her patient(s) with this medicine.
  + He/she will act in accordance with all legal requirements and obligations applicable in Belgium.
  + He/she will comply with all applicable privacy and data security legal requirements in providing any patient information to Amgen.
  + The disease for which the medicinal product is requested is life-threatening and cannot be satisfactorily treated by the medicinal products currently marketed in Belgium and approved for the treatment in this indication.
  + He/she will inform the patient of all aspects of the Compassionate Use program in a clear and complete manner and will obtain informed consent from the patient, at the latest before the start of the treatment with the medicinal product received within the modalities of the Compassionate Use program
  + The patient is eligible for the program, and fulfils following criteria (please tick the appropriate boxes)

|  |  |  |  |
| --- | --- | --- | --- |
|  | CRITERIA | Yes | No |
| INCLUSION CRITERIA | Patients with B–precursor ALL in complete hematological remission defined as less than or equal to 5% blasts in the bone marrow after at least three intense\* chemotherapy blocks blocks (e.g. GMALL induction I-II/consolidation I, induction/intensification/consolidation or three blocks of Hyper CVAD)  \* Age appropriate treatment given with the intention to achieve a complete hematological remission and the best long term outcome at the judgment of the treating physician can be considered as intense chemotherapy treatment. | ☐ | ☐ |
| Presence of minimal residual disease (MRD) at a level of ≥ 10-4 documented after an interval of at least 2 weeks from the last systemic chemotherapy by a validated methodology and test performed in a specialized treatment center with access to laboratory that has expertise in MRD assays | ☐ | ☐ |
| Age ≥ 18 years | ☐ | ☐ |
| Adequate bone marrow function\*\*  \*\* The physician will take into account the degree of hematopoietic recovery from the last previous chemotherapy and decide whether the functional level of bone marrow is adequate or not for blinatumomab use in view of benefits, but also risks. | ☐ | ☐ |
| Patients cannot be satisfactorily treated with the approved and commercially available alternative treatments, in accordance with clinical guidelines, because of efficacy and/or safety issues | ☐ | ☐ |
| EXCLUSION CRITERIA | Presence of circulating blasts or current extra-medullary involvement by ALL | ☐ | ☐ |
| Current infiltration of cerebro-spinal fluid by ALL | ☐ | ☐ |
| History of relevant CNS pathology or current relevant CNS pathology | ☐ | ☐ |
| History of or active relevant autoimmune disease | ☐ | ☐ |
| Eligibility for treatment with TKIs (i.e., Philadelphia chromosome-positive (Ph) patients with no documented treatment failure of or intolerance/contraindication to at least 2 TKIs) | ☐ | ☐ |
| Known hypersensitivity to immunoglobulins or to any other component of the study drug formulation | ☐ | ☐ |
| Breast-feeding | ☐ | ☐ |
| The patient is not eligible for a clinical trial running with blinatumomab and/or a clinical trial running in the envisaged indication of this program | ☐ | ☐ |

* + He/She will report all adverse events (non-serious and serious) and other safety findings by OR faxing a completed, signed and dated Safety Report Form to the Amgen – Belgian Safety Department (Safety fax nr: 0800 80 877 ) within one working day OR mailing a completed, signed and dated Safety Report Form to the email [svc-ags-in-be@amgen.com](mailto:svc-ags-in-be@amgen.com) within one working day.

Initial Request

I hereby request Amgen n.v. to supply BLINCYTO® (blinatumomab) to my patient for individual patient supply in the context of the Compassionate Use program in adult MRD+ B-precursor ALL.

This initial request only covers blinatumomab delivery for maximum 2 cycles (56 packs).

To extend the treatment with 1 cycle of blinatumomab, a Renewal Request Form (including confirmation of compliance with safety reporting) will need to be submitted to Amgen n.v. ([EU\_BE\_blinatumomab@amgen.com](mailto:EU_BE_blinatumomab@amgen.com)).

I confirm that a Patient End of Treatment Form will be submitted in case the patient has stopped treatment.

I hereby confirm that the above mentioned medication will be solely used for the purpose of the program and that any unused medication will be returned to Amgen or destroyed in an appropriate facility.

|  |
| --- |
| **Physician’s signature: …………………………………… Date: …... / ……. / 20….…**  **Physician’s name ...................................................................................................**  **Hospital ...................................................................................................**  **Address ...................................................................................................**  **...................................................................................................**  **Telephone ...................................................................................................**  **Fax ...................................................................................................**  **E-mail (mandatory) ...................................................................................................**  **Email contact person (if applicable)........................................................................** |

**Hospital Pharmacy Responsible Person CU Program**

Name ..…………………………………………………………………………

Pharmacy Department ………………………….…………………………………..

Phone ….…………………………………………………………….…………

FAX …………………………………………………………….……..………

Email ..………………………………………………………………….………

Confirmation of Enrolment

**(To be completed by Amgen n.v.)**

Dear Professor/Doctor …………………………………….,

We are happy to inform you about the positive advice of the responsible physician on the eligibility of your patient. Amgen n.v. hereby confirms the enrolment of your patient in the program.

56 vials of blinatumomab will be sent to the pharmacy.

Please don’t hesitate to contact us for further information.

**Signature Signature date**

**(dd/mm/yyyy)**