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The Secretary
Expert Committee on the Selection and Use of Essential Medicines
Department of Health Products Policy and Standards
Access to Medicines and Health Products Division
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By email: emlsecretariat@who.int

17 April 2025

Dear Expert Committee

RE: Agenda Item **A.5 Blinatumomab - acute lymphocytic leukaemia**

On behalf of Amgen, I would like to acknowledge the efforts of the Committee to assess the addition of relevant medicines to the Model List of Essential Medicines and would be pleased to outline our support for the submission for consideration of blinatumomab on the **WHO Model List of Essential Medicines for Children.** Amgen provided funding to Resonance Inc for the preparation of the submission document and provided information to assist with the preparation of various aspects of the content.

Since initial registration* of blinatumomab (as continuous infusion) in 2014, we have been pleased to expand the approved indications* to the treatment of relapsed/refractory (R/R) B-cell precursor acute lymphoblastic leukemia (ALL) and minimal residual disease (MRD)-positive B-cell precursor ALL. We note the burden of paediatric acute lymphoblastic leukaemia has been addressed comprehensively in the submission, and clinical evidence has also been presented. The evidence presented in the submission supports the benefit and impact of blinatumomab in acute lymphoblastic leukaemia in multiple settings. As we continue to undertake clinical investigations (as do others, such as Children's Oncology Group), we hope to further demonstrate the relevance and impact of blinatumomab to improve outcomes in B-cell acute lymphoblastic leukemia.

As the manufacturer and market authorisation holder for blinatumomab, we have engaged with regulatory and reimbursement agencies around the world to ensure that blinatumomab is able to be introduced into health systems. Blinatumomab has proven its cost-effectiveness in many jurisdictions and has been scrutinised for its relative value for the health system and for improved health outcomes in B-cell acute lymphoblastic leukaemia. In many jurisdictions, as the regulatory label has expanded the reimbursed population has also expanded.

We acknowledge that blinatumomab must be considered in the context of a robust health system that has adopted relevant technologies, including combination chemotherapeutic regimens, considerable pathology capacity including advanced diagnostic capabilities, appropriate advanced radiology, and an appropriately trained workforce. Low-resource country contexts, especially in

paediatric oncology, may not all be able to undertake the complex management of acute lymphoblastic leukaemias with more contemporary medicines like blinatumomab. However, there are examples of sites that can, and do, routinely administer blinatumomab – increasingly so in the middle-income country context. We have also been pleased to collaborate with St Jude Children's Research Hospital on an implementation-focused program with blinatumomab in low-resource settings, and for which a protocol was published in 2022. The collaboration has been steadily increasing provision of relevant care as well as medication in sites across three countries and has recently passed 250 treated individuals.

Similarly, over the recent years Amgen has demonstrated its commitment to improving access to medicines in LMICs in a number of ways, including:

- In 2023, submitting pegfilgrastim for consideration of addition to the WHO Essential Medicines List (for adults and children), which was subsequently recommended for addition
- Making a five-year commitment to support World Child Cancer to improve outcomes for children with cancer, with a specific focus on those affected by B-cell lymphomas, including Burkitt Lymphoma
- Participation in actions supporting the Global Platform for Access to Childhood Cancer Medicines

Amgen acknowledges the importance of the Global Platform for Access to Childhood Cancer Medicines (the "Global Platform") as a complement to the WHO Global Initiative for Childhood Cancer, which more broadly seeks to improve the ability of countries to incorporate childhood cancer management into national cancer control plans. We note that the Global Platform seeks to collaborate across sectors to rapidly increase access to care for thousands of children. The Global Platform is creating a framework for a more predictable basis for childhood cancer management in selected countries, and a focus on end-to-end support for those countries to potentially adopt and provide medicines to children in need.

Should blinatumomab be recommended for addition to the WHO Model List of Essential Medicines for Children, Amgen would be pleased to explore with relevant stakeholders how we may further support the endeavours of the Global Platform for Access for Childhood Cancer Medicines.

Yours sincerely

Paul Burton

Dr Paul Burton

Chief Medical Officer, Amgen

** In countries/ regions where it is registered, blinatumomab is currently supplied as a lyophilised powder in a single-dose vial for reconstitution and for administration as a continuous intravenous infusion at a constant flow rate using an infusion pump.*