April 17, 2025

Secretary of the Expert Committee on the Selection and Use of Essential Medicines
Department of Health Products Policy and Standards (HPS)
World Health Organization
20 Avenue Appia
CH-1211, Geneva 27, Switzerland

Re. Statement of support for the inclusion of blinatumomab in the WHO Essential Medicines List for Children (EMLc)

Dear WHO Expert Committee:

We firmly provide our most enthusiastic support for the inclusion of blinatumomab in the WHO Essential Medicines List for Children (EMLc).

Since 2020 we at the Department of Global Pediatric Medicine at St. Jude Children's Research Hospital ("St. Jude"), Memphis, TN, USA have worked collaboratively with Amgen and a non-governmental organization to increase access to blinatumomab for children with B-cell acute lymphoblastic leukemia (ALL) at institutions in low and middle-income countries (LMIC). In support of the mission of St. Jude, we conducted a hybrid effectiveness-implementation research study with multidisciplinary teams of physicians, nurses, and pharmacists at six institutions in three LMICs (India, Pakistan, and Vietnam) [*Duffy C, et al, Evaluating blinatumomab implementation in low- and middle-income countries: a study protocol. Implement Sci Commun. 2022 June*]. We have demonstrated that with proper implementation support, it is feasible to integrate blinatumomab into standard care at institutions in LMICs with minimal interruptions related to logistics and that multidisciplinary pediatric oncology teams can administer blinatumomab safely to their patients. During our study, we observed the safety and clinical impact across more than 100 pediatric patients and found that blinatumomab can be safely prepared, administered, and managed with similar safety profiles as observed in clinical trials in high-income settings. Furthermore, the patient impact has been gratifying with clinical responses in MRD-positive and relapsed/refractory B-ALL patients [*Duffy C, et al; Evaluating Blinatumomab Treatment Adoption in Varied Resource Settings Using the RE-AIM Framework. Blood 2023; 142 (Supplement 1): 3713. doi: https://doi.org/10.1182/blood-2023-190228*] This complementary implementation and clinical evidence underscores the drug's reliability and effectiveness in resource-limited settings.

The inclusion of blinatumomab in the WHO EMLc is not just a matter of improving treatment options; it is a matter of saving lives. Pediatric cancer patients in LMICs face significant barriers to accessing advanced medical treatments, and the availability of blinatumomab can make a profound difference in their survival and quality of life. By including blinatumomab in the WHO EMLc, we can ensure that children worldwide have access to this essential medicine, regardless of their geographic or economic circumstances.

In conclusion, our work has demonstrated that blinatumomab can be safely administered and is beneficial for the LMIC patient population and should, therefore, be made more available with similar implementation support as we have demonstrated. The inclusion of blinatumomab in the WHO EMLc will be a crucial step towards achieving equitable access to essential medicines for all children, aligning with WHO's mission to improve global health.

Thank you for your consideration. If you would like additional information regarding our research or support of adding blinatumomab to the WHO EMLc, please contact Caitlyn Duffy at caitlyn.duffy@stjude.org.

Sincerely,

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