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Letter of Support – Support for Inclusion of Blinatumomab in the WHO List of Essential Medicines for Children

Dear WHO Expert Committee,

I am writing to express my strong support for the inclusion of blinatumomab on the WHO Essential Medicines List for Children (EMLc) for the treatment of CD19-positive B-cell precursor acute lymphoblastic leukaemia (B-ALL). As a paediatric haematologist, I have seen firsthand the critical need for innovative therapies in the treatment of relapsed and refractory childhood ALL—particularly in low- and middle-income countries (LMICs) where survival disparities remain stark.

The introduction of blinatumomab has significantly changed the treatment landscape for paediatric B-ALL, with multiple phase 3 randomised studies supporting its efficacy and safety:

- The JAMA phase 3 study (Brown et al., 2021) showed that blinatumomab used after reinduction significantly improved 2-year overall survival (71.3% vs. 58.4%) compared to chemotherapy, with far fewer toxicities.
- In the JCO AALL1331 study (Hogan et al., 2023), children with low-risk first relapse involving bone marrow had markedly better outcomes with blinatumomab, including 4-year disease-free survival of 72.7% vs. 53.7%, and overall survival of 97.1% vs. 84.8%.
- Additionally, the Locatelli et al. (JAMA, 2021) randomized phase 3 trial in children with high-risk first relapse showed that a single cycle of blinatumomab before HSCT resulted in a hazard ratio of 0.33 for event-free survival, significantly reducing relapse and improving MRD remission (90% vs. 54%) with fewer high-grade toxicities compared to intensive consolidation chemotherapy.

- The NEJM AALL1731 trial (Lau et al., 2024) demonstrated a significant survival benefit when blinatumomab was added to frontline chemotherapy for standard-risk B-ALL, with 3-year DFS reaching 96.0%, compared to 87.9% with chemotherapy alone.

These data consistently demonstrate that blinatumomab is highly effective across diverse risk groups and treatment phases and offers a safer, more targeted alternative to conventional chemotherapy. In LMICs, where 85% of the global paediatric ALL burden lies, expanding access to blinatumomab could help close long-standing survival gaps. Studies in India and Pakistan have already shown that blinatumomab can be delivered safely and effectively in resource-limited settings. Inclusion on the WHO EMLc would also align with and support the objectives of the WHO Global Initiative for Childhood Cancer and the WHO–St. Jude Global Platform for Access to Childhood Cancer Medicines.

In summary, blinatumomab meets all essential medicine criteria: it saves lives, is supported by robust evidence, and is deliverable worldwide. I strongly urge the Committee to support its inclusion.

Sincerely,

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Co-Chief Investigator Elect
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