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Unser Zeichen:

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Dear EML Secretariat,

As representative of the IntReALL Study Group and Chair of the Study Group for Childhood Relapsed ALL (ALL-REZ BFM) of the German Society of Pediatric Oncology / Hematology (GPOH) I want herewith to support for the submission to include blinatumomab on the WHO List of Essential Medicines for Children.

Blinatumomab has proven to be safe and effective in childhood refractory, relapsed and primary ALL. In all relevant randomized trials, Blinatumomab has shown superior efficacy in addition or as compared to standard of care chemotherapy. Furthermore, it showed better safety profiles as the comparator arms. Several randomized trials had to be stopped preterm due to early superiority of the respective blinatumomab arm.

The IntReALL Study Group supports the early and advanced development of Blinatumomab in childhood relapsed BCP-ALL, and considers the drug as one of the most important milestones on the way of overcoming the life-threatening disease ALL and the devastating side effects of conventional intensive chemotherapy.

Blinatumomab has become important standard of care for consolidation therapy of childhood and adult primary and relapsed B-cell ALL in the USA, and in children with high-risk relapsed BCP-ALL in Europe.

While access to Blinatumomab is largely warranted in developed industrial countries, the drug is hardly available in low- and middle-income countries. Inclusion of Blinatumomab on the EMLc would be an important step to overcome this ethically critical inequality.

Sincerely,

Prof. Dr. med. Arend von Stackelberg

Chair ALL-REZ BFM Study Group, PI IntReALL SR/HR 2010 and BCP 2020

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