

# CD19-targeted chimeric antigen receptor-modified T cells induce remission in patients with relapsed acute B lymphoblastic leukemia after umbilical cord blood transplantation

Qianwen Xu<sup>1</sup>, Hui Xu<sup>2</sup>, Lei Xue<sup>2</sup>, Min Wang<sup>3</sup>, Guifang Pan<sup>3</sup>, Xuhan Zhang<sup>2</sup>, Kaidi Song<sup>2</sup>, Wen Yao<sup>2</sup>, Xiang Wan<sup>2</sup>, Juan Tong<sup>2</sup>, Huilan Liu<sup>2</sup>, Hanying Xu<sup>3</sup>, Xin Liu<sup>2</sup>, Xiao-yu Zhu<sup>2</sup>, Zi-min Sun<sup>2</sup>, Lin Yang<sup>3</sup>, and Xing-bing Wang<sup>1</sup>

<sup>1</sup>Anhui Medical University

<sup>2</sup>The First Affiliated Hospital of USTC

<sup>3</sup>PersonGen-Anke Cellular Therapeutics Co., Ltd.

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## Abstract

**Background** Few therapies are available for treating patients with B acute lymphoblastic leukemia (B-ALL) who relapse after umbilical cord blood transplant (UCBT). Chimeric antigen receptor (CAR)-modified T cell therapy targeting CD19 is novel and effective for treating refractory/relapsed (R/R) hematological malignancies. **Method** We report the response rate, toxicity, and survival of CD19-targeted CAR modified T cells administered to 10 patients with B-ALL who relapsed after UCBT from April 2018 to September 2019. Patients [?]14 years of age were subsequently recruited in the clinical trial (NCT02851589) conducted at the First Affiliated Hospital of USTC, Hefei, China. **Results** Patients (n = 11) were infused with peripheral blood T cells transduced with CD19-directed CAR lentiviral vectors ( $0.42 \times 10^6$ – $3.91 \times 10^6$  cells/kg body weight). Among 10 patients who were successfully infused, 9 achieved minimal residual disease-negative complete remission (MRD-neg CR). As of July 30, 2020, 6 of 10 patients experienced a relapse (median follow-up for CR was 13.2 months, range 5.8–31.7 months). The 6-month rates of progression-free survival (PFS) and overall survival (OS) were 44.4% and 77.8%, respectively. Toxicities were reversible, including severe cytokine release syndrome (CRS) ([?] grade 3) and neurotoxicity in 10% (1/10) and 10% (1/10) of patients, respectively, and no patient experienced graft-versus-host disease (GVHD). **Conclusion** CD19-targeted CAR-modified T cell therapy may therefore serve as a safe and effective approach for treating patients with relapsed B-ALL after UCBT. A multicenter clinical trial including more subjects is required to confirm safety and efficacy.

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