

OLVEREMBATINIB-BASED TREATMENT FOR NEWLY DIAGNOSED PHILADELPHIA CHROMOSOME-POSITIVE ACUTE LYMPHOBLASTIC LEUKEMIA: A MULTI-CENTER RETROSPECTIVE STUDY

Kezhi Huang^{1,2,3#}, Yiqing Li^{1#}, Xuejie Jiang^{4#}, Cong Luo⁵, Zeyu Luo⁵, Wenjuan Yang¹, Hongyun Liu¹, Guoyang Zhang¹, Runhui Zheng⁶, Guinian Huang⁷, Wenzheng Pang⁸, Xueyang Xing⁹, Zhenqian Huang¹⁰, Jixian Huang¹¹, Huashan Luo¹², Danian Nie^{1*}

¹Sun Yat-Sen Memorial Hospital, Sun Yat-Sen University, Guangzhou, China. ²Guangdong Provincial Key Laboratory of Cancer Pathogenesis and Precision Diagnosis and Treatment, Shenshan Medical Center, Sun Yat-sen Memorial Hospital, Sun Yat-sen University, Shanwei, China. ³JieXi People's Hospital, JieYang, China. ⁴The Second Affiliated Hospital of Guangzhou Medical University, Guangzhou, China. ⁵The First Affiliated Hospital, Hengyang Medical School, University of South China, Hengyang, China. ⁶The Fifth Affiliated Hospital of Guangzhou Medical University, Guangzhou, China. ⁷Zhongshan City People's Hospital, Zhongshan, China. ⁸The Fifth Affiliated Hospital, Sun Yat-sen University, Zhuhai, China. ⁹The First Affiliated Hospital of Shantou University Medical College, Shantou, China. ¹⁰The First Affiliated Hospital of Guangzhou Medical University, Guangzhou, China. ¹¹Yuebei People's Hospital, Shaoguan, China. ¹²Meizhou People's Hospital, Meizhou, China.

#These authors are co-first authors



INTRODUCTION

Olverembatinib , a novel third-generation tyrosine kinase inhibitor (TKI), has showed remarkable responses in chronic myeloid leukemia.

AIM

We aim to unravel its role in newly diagnosed Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) .

METHOD

A multi-center retrospective study from south China enrolled 18 patients diagnosed as de novo Ph+ ALL, with a median age 49 years. Olverembatinib was orally administered at 40 or 30 mg once every other day, with reduced-intensity chemotherapy in the frontline therapy.

CONCLUSIONS

Olverembatinib-based regimen with less intensity chemotherapy showed promising outcomes with acceptable side effects as frontline in Ph+ ALL patients, warranting further trials to investigate the better strategies.

RESULTS

From December 2023 to March 2026, a total of 18 patients were enrolled, of which 8 patients (44.4%) were with high risk. Five patients (27.7%) carried BCR-ABL P210 transcript, while the others were P190 positive. The median of WBC was 47.17×10⁹/L (range 0.54-325.6). Aberrance of IKZF1 was detected in 7/18 (38.8%) patients, of which 4 (22.2%) patients were IKZF1 plus. All patients achieved CR after induction. CMR was achieved in 13/15 (86.6%) patients within 3 months. The median time from initiation of Olverembatinib to achieve CMR was 1 month (range 1-7). The median follow-up was 8.5 months (range 2~29). Until the last visit at Apr 30, 2026, all patients survived. Median overall survival was not reached. Treatment related adverse events (TRAEs) at any grade included skin hyperpigmentation (7/18, 38.8%), anemia (6/18, 33.3%), thrombocytopenia (8/18, 44.4%), neutropenia (3/18, 16.6%), pneumonia (3/18, 16.6%), elevated creatinine (1/18, 5.5%), and elevated transaminase (5/18, 27.7%). Not any cardiovascular event was observed.

Outcomes	n=18
CR after induction, n (%)	18 (100%)
CMR within 3 months (BCR-ABL/ABL≤0.01%), n (%)	13/15 (86.6%)
Time from initiation of Olverembatinib to achieve CMR, month, median (range)	1 (1-7)
Follow-up, month, median (range)	8.5 (2-29)
Survival at last visit 2026.04.30, n (%)	18 (100%)
Relapse at gene level, n (%)*	1 (5.5%)

Table 1. Olverembatinib-based regimen with less intensity chemotherapy showed promising outcomes. *Relapsed at gene level after discontinuation of Olverembatinib at 1 month, with a quantity of P210 transcript rising to 0.3%. High risk, IKZF1 deleted and hyper-leukocyte with WBC of 305×10⁹/L at diagnosed.

ACKNOWLEDGEMENTS

This work was supported by grants from Guangdong Science and Technology Department (#2024B1212030002), Natural Science Foundation of Guangdong Province (2025A1515012504), Guangzhou Clinical High-tech, Major and Characteristic Technology Research Fund, China (2023P-TS16).

CONTACT INFORMATION

*Danian Nie

E-mail: niedn@mail.sysu.edu.cn

REFERENCES

1. C Li, et al. Blood Cancer J. 2026
2. M Yuan, et al. Haematologica. 2026
3. X Gong, et al. Leukemia. 2025