

NEWS | TECHNOLOGY

InnoCare Pharma Gains Approval for Phase III Trial of Mesutoclax Combination in Newly Diagnosed AML

China's NMPA approves registrational study comparing mesutoclax plus azacitidine with venetoclax plus azacitidine in elderly or unfit patients with treatment-naïve acute myeloid leukemia, with overall survival as the primary endpoint.

By **Ankit Kankar** | September 13, 2026



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InnoCare Pharma, a leading biopharmaceutical company focusing on the treatment of cancer and autoimmune diseases, announced today that the Center for Drug Evaluation (CDE) of the China National Medical Products Administration (NMPA) has approved the registrational Phase III study of the Company's novel BCL2 inhibitor mesutoclax (ICP-248) in combination with azacitidine versus venetoclax with azacitidine in elderly or unfit patients with treatment naive (TN) acute myeloid leukemia (AML).

The head-to-head randomized, open-label, multicenter registrational Phase III clinical trial is designed to demonstrate the superiority of mesutoclax in combination with azacitidine over venetoclax with azacitidine in elderly or unfit patients with treatment naive AML. The primary endpoint is overall survival (OS).

Mesutoclax is a novel, orally bioavailable BCL2 selective inhibitor. BCL2 is an important regulatory protein in the apoptosis pathway, and its abnormal expression is associated with the development of various hematologic malignancies. Mesutoclax exerts anti-tumor activity by selectively inhibiting BCL2 and restoring the normal apoptosis process in cancer cells. Mesutoclax has been granted two Breakthrough Therapy Designations (BTD) by the CDE.

Data presented at the 2026 American Society of Clinical Oncology (ASCO) Annual Meeting demonstrated that mesutoclax in combination with azacitidine in patients with AML achieved outstanding efficacy and safety. As of April 13, 2026, among the evaluable TN AML patients, 81.8% achieved composite CR (cCR, CR+CRi). Among patients who achieved overall response, 86.5% were MRD (Minimal Residual Disease) negative. Among cCR responders, 83% achieved cCR in the first treatment cycle, demonstrating that the mesutoclax regimen enables rapid and deep remission. In terms of safety, no dose-limiting toxicities (DLTs) were observed, and the maximum tolerated dose (MTD) was not reached. Notably, both 30-day mortality and 60-day mortality were 0% among TN AML patients. At the recommended dose, the 6-month overall survival (OS) rate was 90.5%.

Dr. Jasmine Cui, Co-founder, Chairwoman, and CEO of InnoCare, said, "The efficacy and safety mesutoclax has demonstrated to date give us the confidence to test it head-to-head against the global standard of care. Mesutoclax is one of our key global assets. We have been accelerating the global trial of mesutoclax in combination with azacitidine for AML, with patients enrolled in the U.S. and Australia. We will further advance its clinical development to bring this innovative therapy to more patients worldwide as early as possible."

AML is a malignant hematological disease originating from hematopoietic stem/progenitor cells. The risk of developing AML increases with age and is more common among older adults¹.

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