CCM Biosciences Announces Presentation of Data on its First-In-Class AML Drug Program at ASCO 2025

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Company's AML drug program is focused on both newly diagnosed and relapsed/refractory FLT3-positive AML, overcoming major forms of resistance to FDA-approved FLT3 inhibitors, and outperforms other investigational inhibitors in a wide range of drug resistance models.

MOUNT LAUREL, N.J., May xx, 2025 -- **CCM Biosciences**, a diversified pharmaceutical discovery and development company, today announced the upcoming presentation of its next-generation FLT3 inhibitor drug program for acute myeloid leukemia (AML) at the 2025 Annual Conference of the American Society of Clinical Oncology (ASCO), taking place May 30 to June 3 in Chicago.

Acute Myeloid Leukemia (AML) is the most severe form of leukemia with few treatment options, and a malignancy frequently driven by mutations in the FMS-like tyrosine kinase 3 (FLT3) gene. The FLT3 internal tandem duplication (ITD) and tyrosine kinase domain (TKD) mutations, particularly D835 and F691, appear in approximately 30% of AML patients, often leading to poor prognosis and resistance to existing therapies. Gilteritinib (Xospata®; Astellas Pharma, peak annual sales projection: $1.5 billion) and Quizartinib (Vanflyta®; Daiichi Sankyo) are two FDA-approved FLT3 inhibitors, with the former approved only for relapsed/refractory AML and the latter approved only for newly diagnosed AML. Quizartinib does not target TKD resistance mutations, whereas Gilteritinib's efficacy on FLT3-ITD-D835 mutations is limited and it is not effective against the FLT3-ITD-F691 gatekeeper mutation, both of which are very common. Crenolanib (AROG/Pfizer) is an FLT3 inhibitor whose NDA submitted to the FDA does not address the indications above, whose NDA was previously rejected by the FDA, and which binds to FLT3 mutants less tightly than Gilteritnib. Consequently, there is a critical need for next-generation FLT3 inhibitors that can address all of these mutations.

At ASCO 2025, CCM Biosciences' presentation "Novel, Potent and Selective Inhibitors Targeting FLT3 for AML Therapy" in the *Hematologic Malignancies—Leukemia, Myelodysplastic Syndromes, and Allotransplant* session (Abstract #: 6542, https://www.asco.org/abstracts-presentations/ABSTRACT502974) will report novel FLT3 inhibitors have been identified that can both target FLT3-ITD and potentially overcome mutational resistance to FDA-approved FLT3 inhibitors. These agents are significantly more effective than Gilteritinib and have significant potential clinical applications.

CCM Biosciences' novel, orally bioavailable FLT3 inhibitors (CCM-405 and CCM-445) are the first drug candidates to overcome both FLT3-ITD juxtamembrane domain and tyrosine kinase domain (TKD) mutational drug resistance (including D835Y, F691L), significantly outperforming the aforementioned current-generation inhibitors both in the absence and presence of resistance mutations. Other reported investigational drug candidates capable of addressing FLT3-ITD resistance mutations either have poor pharmacokinetics, significant off-target binding, or both.

CCM Biosciences is advancing clinical candidates from its FLT3 inhibitor program to investigational new drug (IND) filing this year for entry into clinical trials for both newly diagnosed FLT3-positive AML and relapsed/refractory FLT3-positive AML. Multiple failures in AML clinical trials from competitors in 2024 present an attractive landscape for clinical trials of these drug candidates.

The company is actively partnering with biotechnology and pharmaceutical companies for co-development rights in selected countries. CCM Biosciences, a sister company of the global chemical and pharmaceutical services company PMC Group, Inc., is also a Featured Exhibitor at ASCO 2025 -- https://asco25.myexpoonline.com/co/ccm-biosciences -- and will be showcasing both its drug programs and the state-of-the-art platforms used to discover and develop them.

About CCM Biosciences

CCM Biosciences is a diversified biotechnology company dedicated to discovering and developing novel drugs, including small molecules, gene therapies, biologics, and nanomedicines within multiple corporate subsidiaries. CCM's patented drug discovery platforms were developed at **Chakrabarti Advanced Technology**, a privately funded R&D institute founded in 2010 with scientists in the US, France and India and with publications in leading scientific journals including PNAS, Nucleic Acids Research, Physical Review, American Chemical Society journals, Biophysical Society journals, and Nature Publishing Group journals. These platforms are complemented by the contract research, development, and manufacturing organizations (CRDMO) at **PMC Group**, the sister company of CCM Biosciences and a global chemical and pharmaceutical company with ~$1 billion in annual revenue.

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