Apollomics Completes Enrollment in Phase 3 Bridging Study of Uproleselan in Chinese Patients with Relapsed/Refractory Acute Myeloid Leukemia

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FOSTER CITY, Calif., Jan. 03, 2024 (GLOBE NEWSWIRE) -- Apollomics Inc. (Nasdaq: APLM) ("Apollomics" or the "Company"), a clinical-stage biopharmaceutical company developing medicines to address difficult-to-treat cancers, today announced the completion of enrollment in its Phase 3 bridging study evaluating uproleselan (APL-106), an investigational, first-in-class E-selectin antagonist, added to a standard chemotherapy regimen for the treatment of adults with relapsed or refractory acute myeloid leukemia (relapsed/refractory AML).

This Phase 3 bridging study is being performed in China with Chinese r/r AML patients. A total of 140 adult patients across 20 sites in Greater China with primary refractory AML or relapsed AML (first or second untreated relapse) and eligible to receive induction chemotherapy have been randomized to either uproleselan combined with chemotherapy or placebo plus chemotherapy. Apollomics licensed uproleselan from GlycoMimetics (Nasdaq: GLYC), including the rights to clinical development, production and commercial sales in the Greater China market (Mainland China, Hong Kong, Macau and Taiwan).

"Uproleselan, as a potent E-selectin antagonist, is the first in this novel mechanism class to be tested in Phase 3 AML studies, and has the potential to transform the care and positively impact the outcomes of relapsed and refractory AML patients," said Dr. Jianxiang Wang, Chinese Academy of Medical Sciences and Peking Union Medical College, Tianjin, China.

"AML is a highly aggressive hematological cancer, and the prognosis of patients with relapsed or refractory disease is extremely poor. AML remains a major unmet medical need in China with an incidence of close to 40,000 patients every year. Drug combinations targeting tumor-intrinsic and microenvironment-extrinsic pathways of chemoresistance may provide improved outcomes in this disease," said Guo-Liang Yu, Chairman and CEO of Apollomics, Inc. "As a potential first-in-class therapeutic that addresses chemoresistance, uproleselan has the potential to be transformative in patients with AML. I would also like to thank our investigators, staff, as well as our clinical team and CRO partners, for their commitment to completing this important milestone."

The primary endpoint for the Phase 3 bridging study is overall survival. Secondary outcome measures include the rate and duration of remission and whether uproleselan can reduce the rate of oral mucositis, a chemotherapy-related side effect. Additional information on the Phase 3 trial can be found on clinicaltrials.gov (NCT05054543).

About Uproleselan
Uproleselan (APL-106) is an investigational, first-in-class E-selectin antagonist discovered and developed by GlycoMimetics (Nasdaq: GLYC), currently in a broad development program including a late-stage Phase 3 trial in acute myeloid leukemia (AML). Apollomics licensed uproleselan from GlycoMimetics, and Apollomics has the rights to clinical development, production and commercial sales in the Greater China market (Mainland China, Hong Kong, Macau and Taiwan). Uproleselan has received Breakthrough Therapy and Fast Track designations from the U.S. Food and Drug Administration and Breakthrough Therapy designation from the Chinese National Medical Products Administration for the treatment of adult AML patients with relapsed or refractory disease. E-selectin is expressed on the surface of blood vessels, and its binding to myeloid cells confers a pro-survival effect via NF-kB signaling. Uproleselan is being developed to provide a novel approach to disrupting established mechanisms of leukemic cell resistance.

About Apollomics Inc.
Apollomics Inc. is an innovative clinical-stage biopharmaceutical company focused on the discovery and development of oncology therapies with the potential to be combined with other treatment options to harness the immune system and target specific molecular pathways to inhibit cancer. Apollomics currently has a pipeline of nine drug candidates across multiple programs, six of which are currently in the clinical stage of development. Apollomics' lead programs include vebreltinib (APL-101), a potent, selective c-Met inhibitor for the treatment of non-small cell lung cancer and other advanced tumors with c-Met alterations, and uproleselan (APL-106), a specific E-Selectin antagonist that has the potential to be used adjunctively with standard chemotherapy to treat acute myeloid leukemia.

Cautionary Statement Regarding Forward-Looking Statements
This press release includes statements that constitute "forward-looking statements" within the meaning of the federal securities laws, including Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). All statements, other than statements of present or historical fact included in this press release, are forward-looking statements. When used in this press release, the words "potential," "could," "should," "will," "may," "believe," "estimate," "expect," the negative of such terms and other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain such identifying words. Forward-looking statements are based on management's current expectations and assumptions about future events and are based on currently available information as to the outcome and timing of future events. Apollomics cautions you that its forward-looking statements are subject to unknown risks, uncertainties and other factors that could cause actual results to differ materially from those indicated in the Company's forward-looking statements, including: (i) the impact of any current or new government regulations in the United States and China affecting Apollomics' operations and the continued listing of Apollomics' securities; (ii) the inability to achieve successful clinical results or to obtain licensing of third-party intellectual property rights for future discovery and development of Apollomics' oncology projects; (iii) the failure to commercialize product candidates and achieve market acceptance of such product candidates; (iv) the failure to protect intellectual property, and the risk of litigious claims, proceedings, litigation or other types of disputes related to Apollomics' business, licenses or intellectual property; (v) breaches in data security; (vi) the risk that Apollomics may not be able to develop and maintain effective internal controls; (vii) unfavorable changes to the regulatory environment; and those risks and uncertainties discussed in the Annual Report on Form 20-F for the year ended December 31, 2022, filed by Apollomics Inc. with the U.S. Securities and Exchange Commission ("SEC") on April 28, 2023, under the heading "Risk Factors" and the other documents filed, or to be filed, by the Company with the SEC. Additional information concerning these and other factors that may impact the Company can be found in the reports that Apollomics has filed and will file from time to time with the SEC. These SEC filings are available publicly on the SEC's website at www.sec.gov. Forward-looking statements speak only as of the date made by the Company. Apollomics undertakes no obligation to update publicly any of its forward-looking statements to reflect actual results, new information or future events, changes in assumptions or changes in other factors affecting forward-looking statements, except to the extent required by applicable law.

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