



Apollomics, Inc. Receives China Investigational New Drug Approval for APL-106 to Initiate a Phase 3 Bridging Study in Acute Myeloid Leukemia

September 27, 2020 12:00 PM EDT

Foster City, CA, and Hangzhou, China, September 27, 2020 — Apollomics, Inc., an innovative biopharmaceutical company committed to the discovery and development of mono- and combination- oncology therapies, today announced APL-106 (uproleselan) has received Investigational New Drug (IND) approval from the China National Medical Products Administration (NMPA) Center for Drug Evaluation (CDE). This approval enables the initiation of a Phase 1 pharmacokinetic (PK) and tolerability study and includes acceptance of a Phase 3 bridging study of APL-106 in combination with chemotherapy in relapsed/refractory acute myeloid leukemia (AML).

“Our team has worked diligently since licensing APL-106 earlier this year, and receiving China IND approval for our Phase 3 bridging study is a major milestone for Apollomics,” said Guo-Liang Yu, PhD, Co-Founder, Chairman and Chief Executive Officer. “AML is one of the most common leukemias in adults, and there is a strong demand for an effective breakthrough treatment for relapsed/refractory AML. We are pleased that the CDE recognized the need to improve treatment outcomes in this patient population and accepted our Phase 3 bridging study while the Global Phase 3 trial sponsored by GlycoMimetics, our partner, is ongoing. We look forward to initiating our clinical trials in China as we strive to offer a new and effective treatment option for AML patients.”

A comprehensive Phase 3 development program in AML is currently ongoing with uproleselan in the United States by GlycoMimetics. Uproleselan has received Fast Track designation from the U.S. Food and Drug Administration (FDA) as well as Breakthrough Therapy Designation for the treatment of adult AML patients with relapsed or refractory disease. Uproleselan has also been granted Orphan Drug Designation in AML from the FDA and European Union.

About Uproleselan (APL-106)

Discovered and developed by GlycoMimetics, uproleselan (APL-106) is a late clinical stage, first-in-class, targeted inhibitor of E-selectin. Uproleselan (yoo' pro le' sel an) is designed to block E-selectin (an adhesion molecule on cells in the bone marrow) from binding with blood cancer cells as a targeted approach to disrupting well-established mechanisms of leukemic cell resistance within the bone marrow microenvironment. Apollomics licensed APL-106 from Glycomimetics in January 2020. Under the terms of the agreement, Apollomics has the rights and responsibility to develop and commercialize APL-106 in Mainland China, Hong Kong, Macau and Taiwan, also known as Greater China.

About Acute Myeloid Leukemia (AML)

Acute Myeloid Leukemia (AML) is a cancer of the blood and bone marrow. It is an aggressive disease that causes the bone marrow to produce immature cells that are unable to carry out their normal function and develop into leukemic white blood cells called myeloblasts. In the U.S., there are approximately 20,000 new cases of AML each year and a 5-year survival rate of 28.7%.¹ The annual incidence of new cases of AML in China is 21,600, and relapsed/refractory AML has an extremely poor prognosis.²

About Apollomics, Inc.

Apollomics, Inc., incubated by OrbiMed Asia at inception, is an innovative biopharmaceutical company committed to the discovery and development of mono- and combination- oncology therapies to harness the immune system and target specific molecular pathways to eradicate cancer. The company's existing pipeline consists of several development-stage assets, including novel, humanized monoclonal antibodies that restore the body's immune system to recognize and kill cancer cells, and targeted therapies against uncontrolled growth signaling pathways. For more information, please visit www.apollomicsinc.com.

¹National Cancer Institute Surveillance, Epidemiology, and End Results (SEER) Program

²Yang Xiaofeng, Zhang Sufen, Zhang Qingyuan. *Practical Therapeutics of Hematological Diseases[M]. Military Medical Science Press, 2008.*

Contact Information:

Investor Contact:

Wilson W. Cheung
Chief Financial Officer
(650) 209-4436
wcheung@apollomicsinc.com

China Media Contact:

Porda Havas International Finance Communications Group
Terence Wong
General Manager
(852) 3150 6786
terence.wong@pordahavas.com

Ivy Lu
Vice President
(86) 21 3397 8796
ivy.lu@pordahavas.com

U.S. Media Contact:

Remy Bernarda
Corporate Communications
(415) 203-6386
remy.bernarda@apollomicsinc.com