Apollomics Announces the First Approval of Vebreltinib for MET Exon 14 Skip Non-Small Cell Lung Cancer

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Apollomics' partner, Avistone Biotechnology, received approval from Chinese National Medical Products Administration (NMPA) to commercialize vebreltinib (APL-101) in China

Compelling clinical data serving as basis of this approval supports continued development of vebreltinib for the rest of world

FOSTER CITY, Calif., Nov. 16, 2023 (GLOBE NEWSWIRE) -- Apollomics Inc. (Nasdaq: APLM), a late-stage clinical biopharmaceutical company developing multiple oncology drug candidates to address difficult-to-treat and treatment-resistant cancers, today announced that its partner in China, Avistone Biotechnology Co. Ltd., received conditional approval from the National Medical Products Administration (NMPA) of China for the commercialization of vebreltinib to treat patients with MET exon 14 skipping non-small cell lung cancer (NSCLC).

"The NMPA approval of vebreltinib is an important milestone toward providing a new treatment option for patients with MET exon 14 skipping NSCLC in China. Apollomics extends its full support and congratulations to Avistone on this significant achievement," said Guo-Liang Yu, Ph.D., Chairman and Chief Executive Officer of Apollomics. "Our collaboration with Avistone and our ongoing global SPARTA trial with vebreltinib underscores our dedication to developing novel therapies for difficult to treat cancers and drug resistant patients worldwide."

Vebreltinib is a potent, small molecule, orally bioavailable and highly selective c-Met inhibitor. It works by inhibiting the aberrant activation of the HGF/c-Met axis, a key pathway involved in tumor growth, proliferation, and the development of resistance to certain targeted therapies. By targeting c-Met dysregulation, vebreltinib offers a potential breakthrough for patients with MET exon 14 skipping NSCLC and other cancers driven by c-Met alterations, i.e. exon 14 skipping, MET amplification, MET fusions.

In pursuit of the MET exon 14 skipping NSCLC indication, Apollomics is in active discussion with the U.S. Food and Drug Administration (FDA) regarding a New Drug Application (NDA) for vebreltinib based on totality of clinical data from the global SPARTA trial and Avistone's KUNPENG trial in China.

NSCLC accounts for approximately 85% of all lung cancer cases and remains a leading cause of cancer-related deaths worldwide. Patients with MET exon 14 skipping mutations, comprise approximately 3% to 4% of all NSCLC cases, face significant challenges due to limited treatment options.

Under the partnership agreement, Avistone holds the exclusive rights to vebreltinib in China, Hong Kong and Macau, while Apollomics retains the exclusive rights in the rest of the world, including the U.S, and partners have access to each other's data. This collaboration enables both companies to leverage their strengths and maximize the benefit of vebreltinib worldwide.

About SPARTA

Apollomics is conducting a multi-cohort Phase 2 study of vebreltinib, SPARTA, at over 90 centers in 13 countries investigating the efficacy and safety of vebreltinib in MET exon 14 skipping non-small cell lung cancer (NSCLC). Cohorts A-1 is recruiting in first line Met exon 14 skipping NSCLC subjects and Cohort A-2 is recruiting in pretreated (> 2L) MET exon 14 skipping NSCLC subjects. In addition, Cohort C includes histology agnostic cMet amplified cancers (excluding primary CNS tumors) and Cohort C-1 includes NSCLC harboring MET amplification and wild-type epidermal growth factor receptor (EGFR).

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, regarding clinical trials and results, as well as the Company's strategy, business plans and objectives of management are forward-looking statements. In addition, Apollomics cautions you that the forward-looking statements contained in this press release are subject to unknown risks, uncertainties and other factors, 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 Apollomics' intellectual property; (v) breaches in data security; and other risks included in the Annual Report on Form 20-F filed with the SEC and other SEC filings that are available publicly on the SEC's website at www.sec.gov. Apollomics undertakes no obligation to update publicly any of these 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 laws.

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