Apollomics Announces Approval of Vebreltinib in China as a First-in-Class Treatment for Gliomas with MET Fusion Gene

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Apollomics' partner in China, Avistone, received approval from National Medical Products Administration of China to expand the use of vebreltinib to the treatment of gliomas with PTPRZ1-MET fusion gene

Approval based on results from a randomized Phase 2/3 trial

FOSTER CITY, Calif., April 25, 2024 (GLOBE NEWSWIRE) -- Apollomics Inc. (Nasdaq: APLM), a clinical-stage 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. (Avistone), received approval from the National Medical Products Administration (NMPA) of China for vebreltinib (APL-101) for the treatment of adult patients with isocitrate dehydrogenase (IDH) mutant astrocytoma (WHO Grade 4) or glioblastoma with a history of low-grade disease who have the PTPRZ1-MET fusion (ZM fusion) gene and have failed previous treatments. This supplemental New Drug Application (sNDA) approval makes vebreltinib the world's first c-Met inhibitor approved for treatment of Central Nervous System (CNS) tumor with c-Met alteration, and follows the NMPA's November 2023 approval of vebreltinib for the treatment of patients with Met Exon 14 skipping non-small cell lung cancer (NSCLC).

"The NMPA's approval of vebreltinib in gliomas is an important, first-in-class approval as it demonstrates vebreltinib's CNS penetration ability and c-Met inhibitory activity in the tumors there," said Guo-Liang Yu, Ph.D., Chairman and Chief Executive Officer of Apollomics. "Our collaboration with Avistone, which includes data-sharing, and our ongoing global SPARTA trial with vebreltinib underscores our commitment and the potential to develop vebreltinib for treating patients with solid tumors with c-Met alterations globally, outside of China."

Gliomas are difficult-to-treat primary malignant intracranial tumors accounting for about 46% of all intracranial tumors. Surgery, radiation treatment, and chemotherapy are current standard treatment strategies for gliomas with poor prognoses. The overall survival (OS) rate for malignant glioma patients is less than 10% after five years. Prior studies in Chinese patients have found that about 12% of gliomas have MET fusion, among which the representative type ZM fusion occurs in about 14% of glioblastomas with a history of lower-grade disease, often co-occurring with Met Exon 14 skipping mutations, and is associated with a poorer prognosis. The proportion of this glioblastoma genotype in the U.S. and EU is less known.

Vebreltinib, Apollomics' most advanced product candidate in the U.S., is a potent, small molecule, orally bioavailable and highly selective c-Met inhibitor that 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.

The approval of vebreltinib for the ZM fusion-positive glioma indication in China is based on the positive results of Avistone's FUGEN study (NCT06105619), a randomized, two-arm, multicenter Phase 2/3 clinical study that was conducted in China. This 84-patient study compared the efficacy and safety of vebreltinib with the dose-dense regimen of temozolomide or the combination of etoposide and cisplatin, with OS as the primary endpoint. The median OS for the vebreltinib monotherapy regimen was 6.31 months, compared to 3.38 months for the control group, reducing the risk of death by 48% and significantly improving the survival of patients with recurrent relapsing ZM fusion glioma, with an acceptable safety profile.

In the ongoing global SPARTA study being conducted by Apollomics that includes U.S. and European patients, similar to the vebreltinib treated patients in the FUGEN study in China, a median survival of 6.5 months has been observed to date in the 25 patients with recurrent relapsing CNS tumors with c-Met alterations treated with vebreltinib. Eight of these 25 patients with recurrent relapsing glioma had centrally confirmed ZM fusion glioma, where the median OS was also 6.5 months. These preliminary data support cross-region similarity of patient response to treatment with vebreltinib.

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 the 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 12 countries investigating the efficacy and safety of vebreltinib in Met Exon 14 skipping 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 c-Met amplified cancers (excluding primary CNS tumors) and Cohort C-1 includes NSCLC harboring c-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. For more information, please visit www.apollomicsinc.com.

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) Apollomics' ability to raise additional capital to meet its operating cash requirements and expectations regarding incurring net losses and net operating cash outflows; (ii) the ability of Apollomics to maintain the listing of its Class A ordinary shares on Nasdaq (iii) Apollomics' ability to achieve successful clinical results; (iv) Apollomics' ability to commercialize its product candidates; (v) Apollomics' ability to develop and maintain effective internal controls over financial reporting; (vi) the impact of any current or new government regulations in the United States and China affecting Apollomics' operations; (vii) Apollomics' ability to obtain licensing of third-party intellectual property rights for future discovery and development of Apollomics' oncology projects; (viii) 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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