Apollomics Announces Positive Preliminary Data of Vebreltinib in Patients with Non-CNS MET Fusion Solid Tumors from its Phase 2 SPARTA Trial

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43% overall response rate: Six confirmed responses (including one complete response in metastatic non-small cell lung cancer and five partial responses) confirmed by RECIST 1.1 out of 14 patients with solid tumors harboring MET gene fusions

FOSTER CITY, Calif., Aug. 13, 2024 (GLOBE NEWSWIRE) -- Apollomics Inc. (Nasdaq: APLM) ("Apollomics" or the "Company"), a late-stage clinical biopharmaceutical company developing multiple oncology drug candidates to address difficult-to-treat and treatment-resistant cancers, announced today positive preliminary clinical data for the cohort of patients with non-CNS MET fusion solid tumors from the Phase 2 SPARTA trial of vebreltinib.

"We are very pleased with the preliminary data showing 43% objective response rate in patients with non-CNS MET fusion solid tumors. The results in this specific cohort of patients adds to the accumulating evidence supporting the potential of vebreltinib as a highly selective and efficacious treatment against multiple tumor types harboring MET alterations. Alongside the Avistone data for vebreltinib in the treatment of gliblastoma with PTPRZ1 MET fusions, the clinical evidence for the efficacy of vebreltinib in MET fusions is very encouraging," said Guo-Liang Yu, Ph.D., Chairman and Chief Executive Officer of Apollomics. "Based on the overall occurrence of these fusions in 0.1-0.3% of solid tumors, we believe the incidence is several thousand per year in the United States. Given the increasing patient access to next-generation sequencing, we expect it will become increasingly practical to identify and treat these patients with a targeted therapy such as vebreltinb. We look forward to providing additional clinical updates from the SPARTA Phase 2 trial as they become available."

The pivotal SPARTA trial is a global, multi-cohort, single-arm, open label Phase 2 Study evaluating the efficacy and safety of vebreltinib in a range of MET-altered tumors. As of data analysis cutoff date of July 31, 2024, 14 patients with non-CNS MET fusion solid tumors were included in the study: six with non-small cell lung cancer (NSCLC), one with lung sarcomatoid carcinoma, two with intrahepatic bile duct cancer, one with colon cancer, one with pancreatic cancer, one with breast cancer, one with head and neck cancer, and one with esophageal cancer. Two of the 14 were front-line patients without prior systemic therapy, and twelve were second-line or greater. The preliminary clinical efficacy results are based on independent central radiology review using RECIST v1.1 criteria.

Key preliminary clinical data highlights from 14 patients by RECIST v1.1

- 43% objective response rate (ORR): Six confirmed responses by RECIST 1.1 criteria, out of 14 evaluable patients including one complete response in third-line metastatic NSCLC and five partial responses (three patients with NSCLC, one patient in pancreatic cancer, and one patient with intrahepatic bile duct cancer).
- Median overall survival (OS) was 12.4 months and median progression free survival was 4.5 months.
- 5.6 months median duration of response and 3.7 months median time to response. The longest duration of response is 18 months, with that patient currently continuing treatment.

Based on these new data, Apollomics is evaluating opportunities for further development of vebreltinib in patients with MET fusions. Patients currently enrolled in the SPARTA MET fusion cohort will continue with treatment and study follow-up.

About vebreltinib (APL-101)

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 such as osimertinib. By targeting c-MET dysregulation, vebreltinib has demonstrated strong tumor inhibitory effect in a variety of preclinical c-MET dysregulated human gastric, hepatic, pancreatic and lung cancer xenograft animal models and patient-derived xenograft models (PDX).

Details on the Phase 1/2 SPARTA global clinical trial can be found on clinicaltrials.gov: NCT03175224. Apollomics is developing vebreltinib as single-agent cancer therapy in a variety of tumor types and actively assessing the potential of vebreltinib in combination with novel therapies. Vebreltinib recently received conditional approval from the National Medical Products Administration (NMPA) of China and is currently under clinical investigation and not approved for any use in any other regions in the world.

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' lead programs include its core product, 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, which is currently in a Phase 2 multicohort clinical trial in the United States, 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 and other hematologic cancers, which is currently in Phase 1 and Phase 3 clinical trials in China. 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 the Company’s strategy, prospects, plans and objectives are forward-looking statements, including statements about the preliminary data from the Phase 2 SPARTA trial of vebreltinib in patients with non-CNS MET fusion solid tumors. When used in this press release, the words “could,” “should,” “will,” “may,” “believe,” “anticipate,” “intend,” “estimate,” “expect,” “project,” 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. These 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 these forward-looking statements are subject to numerous risks and uncertainties, most of which are difficult to predict and many of which are beyond the control of Apollomics. 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; (vi) the risk that Apollomics may not be able to develop and maintain effective internal controls; (vii) unfavorable changes to the regulatory environment; and (viii) those risks and uncertainties discussed in the Annual Report on Form 20-F for the year ended December 31, 2023, filed by Apollomics Inc. with the U.S. Securities and Exchange Commission (“SEC”) 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 operations and projections discussed herein 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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