Apollomics Presents Interim Data from Two Ongoing Phase 2 Clinical Trials with Vebreltinib in NSCLC Patients with MetExon14 Skipping Mutation

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Treatment of NSCLC patients with MetExon14 skipping mutation with and without co-occurring MET amplification, reflecting "real-world" [1] setting

FOSTER CITY, Calif., Dec. 04, 2023 (GLOBE NEWSWIRE) -- Apollomics Inc. (Nasdaq: APLM) (the "Company"), a late-stage clinical biopharmaceutical company developing multiple oncology drug candidates to address difficult-to-treat and treatment-resistant cancers, today announced the presentation of vebreltinib efficacy and safety data from the ongoing multi-cohort Phase 2 KUNPENG trial (NCT04258033) and the ongoing global multi-cohort Phase 2 SPARTA trial (NCT03175224) at the 2023 IASLC North America Conference on Lung Cancer (NACLC), that was held December 1-3, 2023, in Chicago, Illinois.

Vebreltinib appears efficacious in non-small cell lung cancer (NSCLC) patients with MetExon14 skipping mutation with or without co-occurring MET amplification. Of the 83 NSCLC patients with MetExon14 skipping mutation with available gene copy number (GCN) data from the Phase 2 KUNPENG and SPARTA trials, 91.6% did not have co-occurring MET amplifications, reflecting the real-world distribution of the NSCLC patients with MetExon14 skipping mutation from two large public databases (83.6% and 91.9%)[1]. NSCLC patients with MetExon14 skipping mutation without co-occurring MET amplification (GCN<4) from the KUNPENG and SPARTA trials showed an overall response rate (ORR) of 64.5% and a median duration of response (DOR) of 15.9 months, and those with overlapping MET amplification (GCN≥ 4) achieved ORR of 85.7%. To date, more than 500 patients and 170 healthy volunteers have been dosed with vebreltinib. The safety profile is generally acceptable.

"For the first time, we report the ORR of vebreltinib by GCN in NSCLC patients with MetExon14 skipping mutation. Similar efficacy analyses by GCN subgroup of other cMET inhibitors are either not readily available publicly or were reported to have lower ORR in NSCLC patients with MetExon14 skipping mutation alone without overlapping MET amplification. We are delighted these data from the two ongoing Phase 2 clinical trials showed a potential differentiation from other cMET inhibitors, and suggest vebreltinib has the potential to address patients' unmet medical needs. The distribution of MET amplification status of patients in the NSCLC study with MetExon14 skipping mutation in the vebreltinib program is similar to those reported in U.S. public databases, thus likely close to a real-world setting," said Guo-Liang Yu, Ph.D., co-founder, Chairman and Chief Executive Officer of Apollomics. "Particularly noteworthy is vebreltinib's efficacy in the patient group without co-occurring MET amplification, offering hope for improved outcomes in this challenging-to-treat patient population."

"These interim data demonstrate the activity of vebreltinib in NSCLC patients with MetExon14 skipping mutation, providing robust overall response rates and an acceptable safety profile in patients with and without co-occurring MET amplification," said Siddhartha Devarakonda, M.D., Medical Director of Thoracic Oncology, Swedish Cancer Institute, Seattle, Wash.

Preliminary efficacy and safety data from the Phase 2 KUNPENG and SPARTA trials in patients with MetExon14 skipping mutation is presented in poster PP01.104 titled, "*Vebreltinib Efficacy In MetEx14 Mutant NSCLC With or Without Concurrent MET Amplification, MET GCN Status Distributions Compared With Public Databases*." A copy of the poster will be made available on the Apollomics website following the presentation at ir.apollomicsinc.com/news-events/presentations.

The preliminary data from NSCLC patients with MetExon14 skipping mutation from the KUNPENG and SPARTA trials showed the following efficacy and safety results:

- ORR in patients *without* co-occurring MET amplification (gene copy number<4, n=76) was 64.5%, with median DOR of 15.9 months and Disease Control Rate (DCR) of 88%.
- ORR in patients *with* MET amplification (GCN≥4, n=7) was 85.7%, with DCR of 100%. mDOR was not reached.
- There were only 2 patients with GCN≥6, and both achieved partial response (100%).
- Treatment-related adverse events of grade 3 or higher were reported in 42.2% of patients, with the most common being edema (13.3%) and ALT increase (7.2%).
- Of NSCLC patients with MetExon14 skipping mutation with available GCN data included in this analysis, 91.6% had no co-occurring MET amplification (GCN<4), similar to 83.6% and 91.9% in two public databases[1].

[1]MetExon14 NSCLC patients with available gene copy number (GCN) status available from Project GENIE (n=428) and cBioPortal (n=210) websites (queried 5/8/23) were analyzed to estimate the real-world distribution of MET GCN status in MetExon14 mutated NSCLC.

About vebreltinib (APL-101)

Vebreltinib is a potent, small molecule, orally bioavailable, brain penetrating 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 offers a potential breakthrough for many cancers driven by c-MET alterations.

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). In Phase 1 clinical trials, vebreltinib (bozitinib or PLB1001) demonstrated a generally well-tolerated safety profile with preliminary evidence of clinical activity in NSCLC subjects harboring a mutation that leads to MetExon14 skipping and in secondary glioblastoma multiforme (sGBM) patients harboring MET fusion and/or exon 14 skipping with evidence of brain penetration. In China, vebreltinib is referred to as bozitinib, or PLB1001, where it is being developed by Apollomics' partner Avistone Biotechnology Co. Ltd. KUNPENG study results were presented at the 2023 European Society of Medical Oncology Congress on October 23, 2023. The presentation showed that vebreltinib-treated patients with locally advanced or metastatic NSCLC harboring c-MET exon-14 skipping mutation achieved an overall response rate (ORR) of 75%. Among other notable findings, ORR and DCR were 100% in patients with brain metastases (n=5) and ORR was 66.7% in patients with liver metastases (n=6).

Details on the Phase 1/2 SPARTA global clinical trial can be found on clinicaltrials.gov: NCT03175224. Apollomics is actively assessing the potential of vebreltinib in combination with novel therapies and in a variety of tumor types in addition to developing vebreltinib as single-agent cancer therapy. Vebreltinib recently received conditional approval from the National Medical Products Administration (NMPA) of China.

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 "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 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 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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