Apollomics Inc. Receives FDA Orphan Drug Designation for Vebreltinib (APL-101) for Treatment of Non-Small Cell Lung Cancer with MET Genomic Tumor Aberrations

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FOSTER CITY, Calif., Nov. 15, 2022 (GLOBE NEWSWIRE) -- Apollomics Inc. (Nasdaq: JMAC), an innovative biopharmaceutical company committed to the discovery and development of mono- and combination-oncology therapies, today announced that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation to vebreltinib (APL-101) for the treatment of non-small cell lung cancer (NSCLC) with MET genomic tumor aberrations. The FDA granted the Orphan Drug Designation in August.

“While NSCLC is the most common type of lung cancer, a subset of patients will have MET genomic dysregulations in their tumors which make them more resistant to treatment, presenting an unmet medical need,” said Guo-Liang Yu, PhD, co-founder, Chairman and Chief Executive Officer of Apollomics. “We are pleased to have received the Orphan Drug Designation for vebreltinib, as patients need new and better treatment options. Through genomic testing, we can identify patients who will benefit most from a targeted treatment like vebreltinib. Orphan Drug Designation brings significant developmental benefits to the vebreltinib program, most notably seven-year market exclusivity upon its approval.”

Apollomics’ ongoing global Phase 2 SPARTA study is evaluating vebreltinib in patients with NSCLC and other solid tumors with MET genomic dysregulation.

Dysregulation of the c-MET tyrosine kinase receptor is implicated in the development of tumor malignancy and can arise through several mechanisms, including gene fusion and amplification, overexpression of the receptor and/or its ligand hepatocyte growth factor (HGF), and the acquisition of activating mutations. One type of the activating mutations cause exon 14 to be skipped due to aberrant splicing of MET mRNA. MET exon 14 skipping occurs in approximately 3-4% of NSCLC and has been demonstrated to be an oncogenic driver. MET amplification, another potential oncogenic driver, occurs in ~3% of newly diagnosed NSCLC, as well as in some NSCLC patients treated with targeted TKI therapy, such as EGFR inhibitors, who become treatment resistant.

The FDA’s Office of Orphan Products Development grants orphan designation status to drugs and biologics that are intended for the treatment, diagnosis or prevention of rare diseases, or conditions that affect fewer than 200,000 people in the United States. Orphan Drug Designation provides certain benefits including assistance in the drug development process, tax credits for clinical costs, exemption from FDA Prescription Drug User Fee Act (PDUFA) fees, and seven years of post-approval exclusivity.

As previously announced on Sept. 14, 2022, Apollomics and Maxpro Capital Acquisition Corp. (“Maxpro”) (Nasdaq: JMAC, JMACU, JMACW), announced a definitive agreement for a business combination (the “Transaction” or the “Business Combination”) that would result in Apollomics becoming a publicly traded company on the Nasdaq Global Market (“Nasdaq”). The Business Combination is expected to close in the first quarter of 2023 and Apollomics is expected to be listed on Nasdaq under the ticker symbol “APLM.”

About vebreltinib (APL-101)
Vebreltinib is a novel small molecule kinase inhibitor that targets c-MET. It is a Type 1b class highly selective c-MET inhibitor. 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 (PLB1001) demonstrated a generally well-tolerated safety profile with preliminary evidence of clinical activity in NSCLC subjects harboring a mutation that leads to MET exon 14 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 PLB1001 where it is being developed by Apollomics' partner Beijing Pearl Biotechnology Co. Ltd. Details on the Phase 1/2 SPARTA clinical trial can be found on clinicaltrials.gov: NCT03175224. Apollomics is actively assessing the potential of investigating vebreltinib in combination with novel therapies and in a variety of tumor types in addition to developing vebreltinib as single-agent cancer therapy. Vebreltinib is currently under clinical investigation and not approved for any use anywhere in the world.

About the Phase 2 SPARTA Study
SPARTA is the Phase 2 portion of an ongoing Phase 1/2 international multicenter, open-label study evaluating the safety, pharmacokinetics, and preliminary efficacy of vebreltinib. SPARTA is assessing activity in NSCLC with a mutation that leads to MET exon 14 skipping, and across tumor types (pan-cancer) with MET amplification or fusions. SPARTA is enrolling patients into multiple cohorts. In NSCLC, the trial will evaluate both c-MET inhibitor naïve and experienced patients with mutations that lead to MET exon 14 skipping. Two cohorts will enroll patients with solid tumors with MET amplifications and fusions, including glioblastoma multiforme, the most aggressive form of brain cancer. The primary objective of SPARTA is to assess efficacy by overall response rate (ORR) and duration of response (DOR) per Response Evaluation Criteria in Solid Tumors (RECIST) or relevant evaluation criteria per tumor type. Secondary objectives include the incidence and severity of adverse events and additional efficacy measurements including time to progression, progression free survival, and overall survival.

About Non-Small Cell Lung Cancer (NSCLC)
Lung cancer is a disease in which malignant cancer cells form in the tissues of the lung. In 2017, there were an estimated 558,000 people living with lung and bronchus cancer in the United States, with new cases estimated to be over 228,000 in 2020. Lung cancer is also one of the more deadly cancers with a relative 5-year survival rate of around 20%. NSCLC is the most common type of lung cancer with about 80% to 85% of lung cancers falling into this category.

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 investigating its core product, vebreltinib, 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 developing an anti-cancer enhancer drug candidate, 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.

About Maxpro Capital Acquisition Corp.
Maxpro is a blank check company formed for the purposes of effecting a merger, capital share exchange, asset acquisition, share purchase, reorganization, or similar business combination with one or more businesses in the healthcare and technology industries. In October 2021, Maxpro consummated a $103.5 million initial public offering of 10.35 million units (including the underwriters' full exercise of their over-allotment option), each unit consists of one share of Class A common stock and one redeemable warrant, each warrant entitles the holder to purchase one share of Class A common stock at a price of $11.50 per share. EF Hutton, division of Benchmark Investments LLC, served as the sole book-running manager of Maxpro's initial public offering.

Important Information About the Proposed Business Combination and Where to Find It

For additional information on the proposed Transaction, see Maxpro's Current Report on Form 8-K, filed with the U.S. Securities and Exchange Commission (the "SEC") on September 14, 2022. In connection with the Business Combination, Maxpro and Apollomics intend to file relevant materials with the SEC, including a registration statement on Form F-4 with the SEC, which will include a proxy statement/prospectus, and will file other documents regarding the proposed Transaction with the SEC. Maxpro's stockholders and other interested persons are advised to read, when available, the preliminary proxy statement/prospectus and the amendments thereto and the definitive proxy statement and documents incorporated by reference therein filed in connection with the proposed Business Combination, as these materials will contain important information about Apollomics and Maxpro and the proposed Business Combination. Promptly after the Form F-4 is declared effective by the SEC, Maxpro will mail the definitive proxy statement/prospectus and a proxy card to each shareholder entitled to vote at the meeting relating to the approval of the business combination and other proposals set forth in the proxy statement/prospectus. Before making any voting or investment decision, investors and stockholders of Maxpro are urged to carefully read the entire registration statement and proxy statement/prospectus, when they become available, and any other relevant documents filed with the SEC, as well as any amendments or supplements to these documents, because they will contain important information about the Business Combination. The documents filed by Maxpro with the SEC may be obtained free of charge at the SEC's website at www.sec.gov, or by directing a request to Maxpro Capital Acquisition Corp., 5F-4, No.89, Songren Rd., Xinyi Dist., Taipei City, Taiwan 11073, Attention: Secretary; telephone: +886 2 7713 7952.

Participants in the Solicitation

Maxpro and certain of its directors, executive officers and other members of management and employees may, under SEC rules, be deemed to be participants in the solicitation of proxies from Maxpro's stockholders in connection with the proposed Transaction. A list of the names of those directors and executive officers and a description of their interests in Maxpro will be included in the proxy statement/prospectus for the proposed Business Combination when available at www.sec.gov. Information about Maxpro's directors and executive officers and their ownership of Maxpro securities is set forth in Maxpro's Annual Report on Form 10-K, filed with the SEC on March 31, 2022, as modified or supplemented by any Form 3 or Form 4 filed with the SEC since the date of such filing. Other information regarding the interests of the participants in the proxy solicitation will be included in the proxy statement/prospectus pertaining to the proposed business combination when it becomes available. These documents can be obtained free of charge from the source indicated above.

Apollomics and its directors and executive officers may also be deemed to be participants in the solicitation of proxies from the stockholders of Maxpro in connection with the proposed Business Combination. A list of the names of such directors and executive officers and information regarding their interests in the proposed Business Combination will be included in the proxy statement/prospectus for the proposed Business Combination.

Additional information regarding the participants in the proxy solicitation and a description of their direct and indirect interests will be included in the proxy statement/prospectus filed with the SEC on Form F-4. Stockholders, potential investors and other interested persons should read the proxy statement/prospectus carefully when it becomes available before making any voting or investment decisions. You may obtain free copies of these documents from the sources indicated above.

Cautionary Statement Regarding Forward-Looking Statements

Certain statements in this press release may be considered "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, statements about future financial and operating results, plans, objectives, expectations and intentions with respect to future operations, products and services; and other statements identified by words such as "will likely result," "are expected to," "will continue," "is anticipated," "estimated," "believe," "intend," "plan," "projection," "outlook" or words of similar meaning. These forward-looking statements include, but are not limited to, statements regarding Apollomics' industry and market sizes, expected clinical trial results, future opportunities for Apollomics and Maxpro, Apollomics' estimated future results and the potential transaction between Maxpro and Apollomics, including the implied enterprise value, the expected transaction and ownership structure and the likelihood, timing and ability of the parties to successfully consummate the proposed Transaction.

These forward-looking statements are based upon estimates and assumptions that, while considered reasonable by Maxpro and its management and/or Apollomics and its management, as the case may be, are inherently uncertain and are subject to significant business, economic and competitive uncertainties and contingencies, many of which are difficult to predict and generally beyond the control of Maxpro and Apollomics. Actual results and the timing of events may differ materially from the results anticipated in these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, but are not limited to: the inability to meet the closing conditions to the Business Combination, including the occurrence of any event, change or other circumstances that could give rise to the termination of the Business Combination Agreement; the inability to complete the Transaction due to the failure to obtain approval of Maxpro's stockholders, the failure to achieve the minimum cash condition following any redemptions by Maxpro stockholders, or the failure to meet Nasdaq's initial listing standards in connection with the consummation of the contemplated transactions; costs related to the Transaction; a delay or failure to realize the expected benefits from the Business Combination; risks related to disruption of management's time from ongoing business operations due to the Business Combination; 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; 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; failure to commercialize product candidates and achieve market acceptance of such product candidates; failure to protect Apollomics' intellectual property; breaches in data security; risks related to the ongoing COVID-19 pandemic and response; risk that Apollomics may not be able to develop and maintain effective internal controls; unfavorable changes to the regulatory environment; and other risks and uncertainties indicated in Maxpro's final prospectus dated October 7, 2021 and filed with the SEC on October 8, 2021 for its initial public offering, the Annual Report on Form 10-K, filed with the SEC on March 31, 2022, and the proxy statement/prospectus relating to the Business Combination, including those under "Risk Factors" therein, and in Maxpro's other filings with the SEC. Maxpro and Apollomics caution that the foregoing list of factors is not exclusive.

Actual results, performance or achievements may differ materially, and potentially adversely, from any projections and forward-looking statements and the assumptions on which those forward-looking statements are based. There can be no assurance that the data contained herein is reflective of future performance to any degree. You are cautioned not to place undue reliance on forward-looking statements as a predictor of future performance

as projected financial information and other information are based on estimates and assumptions that are inherently subject to various significant risks, uncertainties and other factors, many of which are beyond the control of Maxpro and Apollomics. All information set forth herein speaks only as of the date hereof in the case of information about Maxpro and Apollomics or the date of such information in the case of information from persons other than Maxpro or Apollomics, and Maxpro and Apollomics disclaim any intention or obligation to update any forward looking statements as a result of developments occurring after the date of this communication. Forecasts and estimates regarding Apollomics' industry and end markets are based on sources Maxpro and Apollomics believe to be reliable, however there can be no assurance these forecasts and estimates will prove accurate in whole or in part. Annualized, pro forma, projected and estimated numbers are used for illustrative purpose only, are not forecasts and do not reflect actual results.

No Offer or Solicitation

This press release is for informational purposes only and shall not constitute a solicitation of a proxy, consent or authorization with respect to any securities or in respect of the Business Combination. This press release also shall not constitute an offer to sell or the solicitation of an offer to buy any securities pursuant to the Business Combination or otherwise, nor shall there be any sale of securities in any jurisdiction in which the offer, solicitation or sale would be unlawful prior to the registration or qualification under the securities laws of any such jurisdiction. No offer of securities shall be made except by means of a prospectus meeting the requirements of Section 10 of the Securities Act of 1933, as amended, or an exemption therefrom.

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