Purple Biotech Announces Positive Late-Breaking Interim Randomized Phase 2 Data at ASCO 2024 Demonstrating CM24 Improved Overall Survival and other Efficacy Endpoints in Pancreatic Cancer

- *26% reduction in risk of death (HR=0.74) and 28% risk reduction in progression or death (HR=0.72) in previously-treated patients administered with CM24+nivolumab+Nal/IRI/5FU/LV vs. standard-of-care(SoC) based on preliminary interim data*
- *Prolongation of 2.1 months in median overall survival (OS) and 1.9 months in median progression-free survival (PFS) in the CM24+nivolumab+Nal-IRI/5FU/LV regimen vs. standard-of-care*
- *Data supported by higher objective response rate (ORR) (25% vs 7%), disease control rate (DCR) (63% vs 40%), and decrease in CA19-9 level (61% decrease vs. 34% increase)*

REHOVOT, Israel, June 01, 2024 (GLOBE NEWSWIRE) -- Purple Biotech Ltd. ("Purple Biotech" or "the Company") (NASDAQ/TASE: PPBT), a clinical-stage company developing first-in-class therapies that harness the power of the tumor microenvironment and immune system to overcome tumor immune evasion and drug resistance, today announced positive interim data from its randomized, controlled, open label, multicenter Phase 2 study of CM24 in second-line metastatic pancreatic ductal adenocarcinoma (PDAC) presented at a late-breaking abstract poster presentation at the 2024 American Society of Clinical Oncology (ASCO) Annual Meeting.

"These exciting interim data demonstrate the potential of CM24 in combination with nivolumab plus the standard-of-care chemotherapy regimen Nal-IRI/5FU/LV to improve clinical outcomes for advanced metastatic PDAC patients. We are highly encouraged by the meaningful results of our primary endpoint, Overall Survival, as well as by the concordant and consistent improvement in all secondary endpoints including PFS, ORR, DCR and CA19-9" stated Gil Efron, Chief Executive Officer of Purple Biotech.

Michael Cecchini, MD Assistant Professor of Medicine at the Yale Cancer Center, a principal investigator in this study, commented, "As a clinician, it is encouraging to see these interim data in the Nal-IRI arm suggesting the potential for improved clinical outcomes for patients with late-stage metastatic PDAC who are in dire need of new effective therapies. These patients face very limited time with their families, and the prospect of potentially lengthening their lives while delaying their disease progression by approximately two months overall is clinically meaningful. These data justify further investigation of CM24 in combination with nivolumab together with standard-of-care chemotherapy to potentially improve outcomes for patients facing a very poor prognosis from this type of tumor".

The Phase 2 study is evaluating CM24, a novel first-in-class multi-functional anti-CEACAM1 antibody, in combination with Bristol Myers Squibb's immune checkpoint inhibitor nivolumab plus SoC chemotherapy in second-line PDAC patients versus SoC chemotherapy alone. CM24 is a humanized monoclonal antibody that blocks CEACAM1, an immune checkpoint protein responsible for tumor immune evasion and poor tumor response and/or resistance to immune checkpoint inhibitors. The primary endpoint of the study is OS and the secondary endpoints include PFS, ORR and DCR. A Bayesian methodology was used to estimate the magnitude of effect of the experimental arm versus the SoC arm and the study is not powered for hypothesis testing. A total of 63 patients have been enrolled, across 18 centers in the U.S., Spain, and Israel in 2 parallel independent randomized study cohorts (total of 2 arms per cohort). The experimental arms administered patients with CM24 plus nivolumab and a choice of one of two SoC chemotherapies for second-line PDAC, dependent on prior first line therapy regimen; either gemcitabine/nab-paclitaxel or liposomal irinotecan (Nal-IRI)/5-fluorouracil (5-FU) and leucovorin (LV) (Nal-IRI/5FU/LV), while the control arms administered either respective chemotherapy alone. CA19-9 as well as additional exploratory biomarkers are also being evaluated. Of the 63 patients enrolled, 32 were in the gemcitabine/nab-paclitaxel study (experimental and control) and 31 were in the Nal-IRI/5FU/LV study (experimental and control). An analysis of the gemcitabine/nab-paclitaxel study will be performed when the data are sufficiently mature. Topline final data are expected by the end of 2024.

The study interim efficacy results as of the cutoff date of May 8, 2024, are summarized in the following table:

Metric	CM24 + Nivolumab + Nal/IRI/5FU/LV Arm (n = 16)	Nal/IRI/5FU/LV Arm (n = 15)
Hazard ratio for OS	0.74 (**95% CI: 0.31-1.77**)	
Median OS	7.72 months	5.62 months
6 months OS rate	53%	39%
Hazard Ratio for PFS	0.72 (**95% CI: 0.33-1.60**)	
Median PFS	3.8 months	1.9 months
3 months PFS rate	60%	47%
6 months PFS rate	19%	10%
ORR	25%	7%
DCR	63%	40%

A consistent and continuous decrease of CA19-9, a validated and clinically predictive PDAC biomarker, was observed in the experimental arm (61% on average) vs. an increase in the control arm (34% on average).

The CM24+nivolumab+Nal/IRI/5FU/LV regimen was well tolerated, with the most frequent treatment emergent Grade 3 or higher adverse

events being diarrhea (19%), fatigue (19%) and anemia (6%).

About Purple Biotech

Purple Biotech Ltd. (NASDAQ/TASE: PPBT) is a clinical-stage company developing first-in-class therapies that seek to overcome tumor immune evasion and drug resistance. The Company's oncology pipeline includes NT219, CM24 and IM1240. NT219 is a dual inhibitor, novel small molecule that simultaneously targets IRS1/2 and STAT3. A Phase 1 dose escalation study is being concluded and a Phase 2 study of NT219 at its recommended Phase 2 level in combination with cetuximab in patients with recurrent and/or metastatic squamous cell carcinoma of the head and neck cancer (SCCHN) is planned. CM24 is a humanized monoclonal antibody that blocks CEACAM1, an immune checkpoint protein that supports tumor immune evasion and survival through multiple pathways. The Company is advancing CM24 as a combination therapy with anti-PD-1 checkpoint inhibitors in a Phase 2 study for the treatment of pancreatic ductal adenocarcinoma (PDAC). The Company has entered into a clinical collaboration agreement with Bristol Myers Squibb for the Phase 2 clinical trials to evaluate the combination of CM24 with the PD-1 inhibitor nivolumab in addition to chemotherapy. The Company is also advancing a preclinical platform of conditionally-activated tri-specific antibodies that engage both T cells and NK cells to induce a strong, localized immune response within the tumor microenvironment. The cleavable capping technology confines the compound's therapeutic activity to the local tumor microenvironment, and thereby potentially increases the anticipated therapeutic window in patients. The third arm of the antibody specifically targets the Tumor Associated Antigen (TAA). The technology presents a novel mechanism of action by unleashing both innate and adaptive immune systems to induce an optimal anti-tumor immune response. IM1240 is the platform's lead tribody in development that targets 5T4 expressed in a variety of solid tumors and is correlated with advanced disease, increased invasiveness and poor clinical outcomes. The Company's corporate headquarters are located in Rehovot, Israel. For more information, please visit https://purple-biotech.com/.

Forward-Looking Statements and Safe Harbor Statement

Certain statements in this press release that are forward-looking and not statements of historical fact are forward-looking statements within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements include, but are not limited to, statements that are not statements of historical fact, and may be identified by words such as "believe", "expect", "intend", "plan", "may", "should", "could", "might", "seek", "target", "will", "project", "forecast", "continue" or "anticipate" or their negatives or variations of these words or other comparable words or by the fact that these statements do not relate strictly to historical matters. You should not place undue reliance on these forward-looking statements, which are not guarantees of future performance. Forward-looking statements reflect our current views, expectations, beliefs or intentions with respect to future events, and are subject to a number of assumptions, involve known and unknown risks, many of which are beyond our control, as well as uncertainties and other factors that may cause our actual results, performance or achievements to be significantly different from any future results, performance or achievements expressed or implied by the forward-looking statements. Important factors that could cause or contribute to such differences include, among others, risks relating to: the plans, strategies and objectives of management for future operations; product development for NT219, CM24 and IM1240; the process by which such early stage therapeutic candidates could potentially lead to an approved drug product is long and subject to highly significant risks, particularly with respect to a joint development collaboration; the fact that drug development and commercialization involves a lengthy and expensive process with uncertain outcomes; final results from clinical studies, including our NT219 and CM24 studies, may vary from the interim analysis, our ability to successfully develop and commercialize our pharmaceutical products; the expense, length, progress and results of any clinical trials; the impact of any changes in regulation and legislation that could affect the pharmaceutical industry; the difficulty in receiving the regulatory approvals necessary in order to commercialize our products; the difficulty of predicting actions of the U.S. Food and Drug Administration or any other applicable regulator of pharmaceutical products; the regulatory environment and changes in the health policies and regimes in the countries in which we operate; the uncertainty surrounding the actual market reception to our pharmaceutical products once cleared for marketing in a particular market; the introduction of competing products; patents obtained by competitors; dependence on the effectiveness of our patents and other protections for innovative products; our ability to obtain, maintain and defend issued patents; the commencement of any patent interference or infringement action against our patents, and our ability to prevail, obtain a favorable decision or recover damages in any such action; and the exposure to litigation, including patent litigation, and/or regulatory actions; the impact of the economic, public health, political and security situation in Israel, the U.S. and other countries in which we may operate or obtain approvals for our products or our business, and other factors that are discussed in our Annual Report on Form 20-F for the year ended December 31, 2023 and in our other filings with the U.S. Securities and Exchange Commission ("SEC"), including our cautionary discussion of risks and uncertainties under "Risk Factors" in our Registration Statements and Annual Reports. These are factors that we believe could cause our actual results to differ materially from expected results. Other factors besides those we have listed could also adversely affect us. Any forward-looking statement in this press release speaks only as of the date which it is made. We disclaim any intention or obligation to publicly update or revise any forward-looking statement or other information contained herein, whether as a result of new information, future events or otherwise, except as required by applicable law. You are advised, however, to consult any additional disclosures we make in our reports to the SEC, which are available on the SEC's website, https://www.sec.gov.

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