Purple Biotech Receives Intention to Grant a European Patent Covering NT219 Combinations with Immunotherapies or MEK Inhibitors to Overcome Tumor Resistance

A Phase 2 study for NT219 in combination with immunotherapy is being conducted in collaboration with the University of Colorado

REHOVOT, Israel, Sept. 09, 2025 (GLOBE NEWSWIRE) -- Purple Biotech Ltd. ("Purple Biotech" or "the Company") (NASDAQ/TASE: PPBT), a clinical-stage company developing first-in-class therapies that seek to overcome tumor immune evasion and drug resistance, today announced that the Examining Division of the European Patent Office has issued an intention to grant a European Patent for Application No. 20168234.1, titled *'Combinations of IRS/STAT3 Dual Modulators and Anti-Cancer Agents for Treating Cancer'*.

This application, if granted, is expected to provide broad protection for NT219 combinations with leading immunotherapies, such as anti-PD-1, PD-L1, CTLA-4, and CD20 antibodies, which are designed to enhance responsiveness in resistant cancers. It further covers combinations of NT219 with MEK inhibitors that may expand treatment sensitivity for resistant tumors. Finally, the application includes claims for combinations of NT219 with selected chemotherapies or targeted agents to address cancers that develop resistance driven by KRAS amplification or mutation. The patent term, excluding extensions, runs through 2036.

"NT219 covalently binds to Insulin Receptor Substrate (IRS1/2), leads to IRS1/2 degradation, and blocks STAT3; both targets are key drivers of drug resistance and tumor immune evasion. We believe that combining NT219 with leading immunotherapies could represent a significant opportunity to thwart cancer's natural ability to develop resistance mechanisms," said Gil Efron, CEO of Purple Biotech. "A Phase 2 study in squamous cell carcinoma of the head and neck (SCCHN) was initiated, evaluating NT219 in combination with either pembrolizumab as proof of concept for the combination with immunotherapy, or in combination with cetuximab where we observed activity in a Phase 1 study."

A comprehensive preclinical package supports the Phase 2 clinical study, demonstrated the synergistic activity of NT219 with immunotherapy in suppressing refractory tumors across multiple indications, showing conversion of the tumor microenvironment from immunosuppressive to immunoreactive (as reported at AACR 2023 and AACR 2025).

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 CAPTN-3, CM24 and NT219. The Company is advancing CAPTN-3, a preclinical platform of conditionally activated tri-specific antibodies, which 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, thereby potentially increasing the anticipated therapeutic window in patients. The third arm specifically targets the Tumor Associated Antigen (TAA). The technology presents a novel mechanism of action by unleashing both innate and adaptive immune systems to mount an optimal anti-tumoral immune response. IM1240 is the first tri-specific antibody in development that targets the 5T4 antigen, which is expressed in a variety of solid tumors and is associated with advanced disease, increased invasiveness, and poor clinical outcomes. IM1305 is the second tri-specific antibody from the platform and targets the TROP2 TAA.

CM24 is a humanized monoclonal antibody that blocks CEACAM1, which supports tumor immune evasion and survival through multiple pathways. CEACAM1 on tumor cells, immune cells and neutrophil extracellular traps is a novel target for the treatment of multiple cancer indications. As proof of concept of these novel pathways, the Company completed a Phase 2 study for the treatment of pancreatic ductal adenocarcinoma (PDAC) with CM24 as a combination therapy with the anti-PD-1 checkpoint inhibitor nivolumab and chemotherapy, demonstrating clear and consistent improvement across all efficacy endpoints and the identification of two potential serum biomarkers and other potential tissue biomarkers. NT219 is a dual inhibitor, novel small molecule that simultaneously targets IRS1/2 and STAT3. A Phase 1 dose escalation study was concluded as a monotherapy and in combination with cetuximab, in which NT219 demonstrated anti-tumor activity in combination with cetuximab in second-line patients with recurrent and/or metastatic squamous cell carcinoma of the head and neck (R/M SCCHN). A Phase 2 study in collaboration with the University of Colorado, to treat R/M SCCHN patients with NT219 in combination with cetuximab or pembrolizumab was initiated. 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; 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, and other factors that are discussed in our Annual Report on Form 20-F for the year ended December 31, 2024 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 on 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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