Purple Biotech Announces New Data Supporting the Unique Design of CAPTN-3 Tri-Specific Antibody IM1240 in Collaboration with the Icahn School of Medicine at Mount Sinai

Mt. Sinai Principal Investigator, Dr. Amir Horowitz, demonstrates tumor cell death induced by IM1240 in patient-derived treatment-resistant head and neck biopsies

Synergistic effects were observed between the NK and the T cell engager arms of IM1240, a unique combination in the CAPTN-3 platform

Analysis of approximately 26,000 human transcriptomes suggests that NKG2A expression is consistently accompanied by 5T4 in solid tissues, but not in blood, supporting the design of IM1240

IM1240, the first CAPTN-3 tri-specific antibody targeting 5T4, a novel tumor-associated antigen, advances toward first-in-human clinical trials, with IND submission planned for 2026

REHOVOT, Israel, Sept. 04, 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 new data on its CAPTN-3 tri-specific antibody IM1240 generated in the laboratory of Dr. Amir Horowitz of the Tisch Cancer Institute at the Icahn School of Medicine at Mount Sinai.

“The collaboration with Dr. Horowitz, a leading expert in cancer immunology and immunotherapy, enables us to evaluate the effects of the CAPTN-3 antibody on patient-derived tumor biopsies, where tumor cell heterogeneity, the immune cell array and other tumor microenvironment (TME) components are preserved, providing a reliable representation of the clinical condition of a patient. Dr. Horowitz’s research is assessing the efficacy and mechanism of action of the CAPTN-3 antibody in several cancer types, including treatment-resistant Non-Small Cell Lung Cancer (NSCLC), head and neck squamous cell carcinoma (HNSCC), and bladder cancer, which represent areas of significant unmet medical need,” said Gil Efron, CEO of Purple Biotech.

Using fresh biopsies of HNSCC patients who have acquired resistance to anti-PD1 therapy, Dr. Horowitz’s results have shown induction of cancer cell apoptosis by the tri-specific IM1240 (capped-CD3x5T4xNKG2A), while none of the related variant bispecifics, having either a non-functional CD3 arm (5T4xCD3) or NKG2A arm (5T4xNKG2A), showed an effect. The results correlate with patient-derived NSCLC tumor explants previously reported and suggest a synergistic effect of the CD3 and the NKG2A arms, a design which is unique to Purple’s CAPTN-3 platform.

“Targeting NKG2A offers a selective checkpoint inhibition strategy that enhances antitumor cytotoxicity while minimizing off-target immune activation. The selective expression of NKG2A mainly on cytotoxic lymphocytes such as Natural Killer (NK) cells and $CD8^+$ cytotoxic T cells (CTLs), makes NKG2A blockade a potentially safer approach compared with other checkpoint inhibitors, and a complementary therapy which acts synergistically with the CD3 engager function of CAPTN-3” commented Dr. Horowitz. “Additionally, robust data analysis representing of approximately 26,000 human transcriptomes across most solid tissues suggests that NKG2A expression is consistently accompanied by both HLA-E and 5T4 in solid tissues, but not in blood, supporting the design of IM1240 that targets 5T4 and potentially reducing safety concerns.”

At the American Society of Gene and Cell Therapy’s (ASGCT) Annual Meeting earlier this year, Dr. Horowitz presented the role of the NKG2A/HLA-E axis in different applications and outlined the unique design and potential advantages of Purple Biotech’s CAPTN-3 T-cell and NK-cell engager platform as a novel immunotherapeutic strategy. He highlighted that the masked-CD3xNKG2AxTAA (tumor associated antigen) trispecific antibodies block the HLA-E/NKG2A checkpoint and enable the activation of NKG2A-expressing immune cell subsets, which are known to have high anti-tumor activity. The conditional activation of the masked CD3 binding site is designed to emphasize the safety profile with enhanced efficacy through cooperation with the NKG2A arm, due to the high expression of NKG2A, HLA-E, and 5T4 in the TME.

Dr. Horowitz is an Associate Professor of Immunology & Immunotherapy and Oncological Sciences, at the Icahn School of Medicine at Mount Sinai, The Lipschultz Precision Immunology Institute and The Tisch Cancer Institute in New York. His research focuses on harnessing NK and CD8 T cells for antitumor effector functions and has demonstrated a novel immunotherapeutic target axis involving the interaction between HLA-E expressing tumor cells and NKG2A-positive NK and CD8 T cells, which suppresses immune responses in treatment-resistant patients. Dr. Horowitz and others have demonstrated that the HLA-E/NKG2A axis is a dominant inhibitory checkpoint pathway in solid tumors and metastasis.

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. 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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