

Kitov Pharma Receives Notice of Allowance for a U.S. Patent Covering its Anti-Cancer Drug Candidate, NT219

Patent covers NT219's combinations with multiple 2nd and 3rd generation EGFR inhibitors, including osimertinib (TAGRISSO®)

TEL AVIV, Israel, Oct. 27, 2020 (GLOBE NEWSWIRE) -- Kitov Pharma Ltd. ("Kitov") (NASDAQ/TASE: KTOV), a clinical-stage company advancing first-in-class therapies to overcome tumor immune evasion and drug resistance, today announced receipt of a Notice of Allowance from the U.S. Patent and Trademark Office (USPTO) for a patent application entitled "Combinations of IRS/STAT3 Dual Modulators and Anti-Cancer Agents for Treating Cancer". The patent, which expires in 2036, covers Kitov's NT219, a dual inhibitor, novel small molecule targeting IRS1/2 and STAT3, important oncogenic drivers and major drug resistance pathways in many hard-to-treat cancers.

The patent application covers the various combinations of NT219 with multiple 2nd and 3rd generation EGFR inhibitors, including osimertinib (TAGRISSO®), a 3rd generation EGFR inhibitor approved in the U.S. for first-line treatment of EGFR-mutated non-small-cell lung carcinoma (NSCLC) with annual sales of more than \$3 billion worldwide. In *in-vitro* studies using NSCLC cells with mutated EGFR (T790M), NT219 was shown to downregulate IRS1 and STAT3, and to synergize with osimertinib in suppressing cell proliferation. In addition, in a preclinical PDX model originated from osimertinib-resistant metastatic NSCLC, NT219 has demonstrated significant single-agent activity, and the combination of NT219 with osimertinib resulted in a synergistic effect, showing strong and statistically significant inhibition of tumor growth, compared to the use of osimertinib alone. These encouraging results suggest a potentially promising therapeutic avenue for NT219 that Kitov intends to explore in future clinical trials.

"We are very pleased with this new addition to our patent coverage in the U.S. for NT219, a potential treatment for many hard-to-treat cancers," said Isaac Israel, Kitov's Chief Executive Officer. "This is an important milestone that has strengthened our extensive IP portfolio and supports our goal of establishing a potential key market for NT219 in the U.S. We expect top-line data readout from our Phase 1/2 trial with NT219 in the second half of 2021."

Kitov recently initiated a Phase 1/2 trial evaluating NT219 as monotherapy treatment of advanced solid tumors, as well as in combination with cetuximab for the treatment of recurrent and/or metastatic squamous cell carcinoma of the head and neck (SCCHN) or colorectal adenocarcinoma. Preliminary data from part one of the study encompasses a dose-escalation evaluation of NT219 monotherapy administered weekly in patients with refractory advanced solid tumors and is expected in the second half of 2021.

About Kitov Pharma

Kitov Pharma Ltd. ("Kitov"; NASDAQ/TASE: KTOV) is a clinical-stage company focusing on advancing first-in-class therapies to overcome tumor immune evasion and drug resistance, to create successful long-lasting treatments for people with cancer. Kitov's oncology pipeline includes NT219 and CM24. NT219 is a small molecule targeting the novel cancer drug resistance pathways IRS1/2 and STAT3. Kitov is currently advancing NT219 as a monotherapy treatment of advanced solid tumors and in combination with cetuximab for the treatment of recurrent or metastatic squamous cell carcinoma of head and neck cancer (SCCHN) in a Phase 1/2 study. CM24 is a monoclonal antibody blocking CEACAM1, a novel immune checkpoint that supports tumor immune evasion and survival through multiple pathways. Kitov plans to advance CM24 as a combination therapy with anti-PD1 checkpoint inhibitors in selected cancer indications in a Phase 1 study followed by a Phase 2 study for the treatment of non-small cell lung cancer NSCLC and pancreatic cancer. Kitov has entered into a clinical collaboration agreement with Bristol Myers Squibb Company for the planned Phase 1/2 clinical trials to evaluate the combination of CM24 with the PD-1 inhibitor nivolumab (Opdivo®). Kitov is also the owner of Consensi®, a fixed-dose combination of celecoxib and amlodipine besylate for the simultaneous treatment of osteoarthritis pain and hypertension that was approved by the FDA for marketing in the U.S. Consensi® is being sold in the U.S. by Burke Therapeutics, the marketing partner of Kitov's U.S. distributor Coepris Pharmaceuticals. Kitov has also partnered to commercialize Consensi in China and South Korea. The company is headquartered in Tel Aviv, Israel. For more information, please visit <http://www.kitovpharma.com>.

Forward-Looking Statements and Kitov's 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 and CM24; the process by which early stage therapeutic candidates such as NT219 and CM24 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, 2019 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, <http://www.sec.gov>.

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