

Kitov Announces Dosing of First Patient in Phase 1/2 Clinical Trial of NT219 in Advanced Cancer Patients

Top Line Results from First Part of the Study Expected in Second Half of 2021

TEL AVIV, Israel, September 8, 2020 -- 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 that the first patient has been dosed in the Phase 1/2 clinical trial of 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 dosing of the first patient in this important study represents a significant milestone for Kitov," said Bertrand Liang, M.D., Ph.D., Chief Medical Officer of Kitov. "Based on the encouraging pre-clinical data generated by NT219 as both monotherapy and in combination with several anti-cancer drugs, we believe that this promising drug candidate has the potential to be a safe and effective therapy for multiple hard-to-treat cancers. We are satisfied with the progress of the study and anticipate full enrollment in this first part of the study as planned, with top line data from the first part of the study expected in the second half of 2021."

The Phase 1/2 trial is evaluating NT219 as monotherapy treatment of advanced solid tumors, as well as in combination with cetuximab, an epithelial growth factor receptor (EGFR) blocking monoclonal antibody, for the treatment of recurrent and/or metastatic solid tumors and head and neck cancer or colorectal adenocarcinoma.

The primary objectives of the open-label Phase 1/2 trial are to evaluate safety, assess pharmacokinetics, identify the recommended dose to be studied in the Phase 2 portion, and establish preliminary efficacy of NT219. The Phase 1 portion of the study will encompass a dose escalation evaluation of NT219 monotherapy administered weekly in patients with refractory advanced solid tumors. Upon reaching the third dose level of NT219, a second cohort of patients, with recurrent or metastatic squamous cell carcinoma of the head and neck or colorectal adenocarcinoma, will be administered weekly with NT219, dose escalated, in combination with cetuximab.

Upon completion of the monotherapy and combination therapy Phase 1 portions of the trial and establishment of the recommended Phase 2 dose for NT219, Kitov plans to commence an expansion Phase 2 component of the study at that dose in combination with cetuximab in patients with recurrent or metastatic squamous cell carcinoma of the head and neck. The trial will also include exploratory evaluations of different potential biomarkers in patient tumors and serum. Further Phase 2 arms in patients with different malignancies, as a monotherapy or in combination with other cancer therapies, will be considered based on the exploratory evaluations and the data generated during the Phase 1 portions of the trial.

The study is anticipated to be conducted at multiple medical centers in North America.

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 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, Coeptis 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 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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