Kitov to Present Preclinical Data on NT219 at American Association of Cancer Research Virtual Annual Meeting II

Company Expects to Initiate Phase 1/2 Trial of NT-219 as Monotherapy Treatment of Advanced Solid Tumors and in Combination with cetuximab for Treatment of Recurrent or Metastatic Solid Tumors and Head and Neck Cancer

TEL AVIV, Israel, May 19, 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 that preclinical data for NT219, a novel agent addressing treatment resistance in advanced cancer, will be presented in a poster at the American Association of Cancer Research (AACR) Virtual Meeting II.

The presentation, titled, "*NT219, a novel dual inhibitor of STAT3 and IRS1/2, demonstrates anti-tumor activity with and without cetuximab in pembrolizumab-resistant head and neck cancer PDX models*," includes preclinical data on NT219, a first-in-class, dual inhibitor of signal transducer and activator of transcription 3 (STAT3) and insulin receptor substrate 1 and 2 (IRS1/2), which have been associated with treatment resistance in a variety of cancer settings. Using multiple patient derived xenograft (PDX) models of subjects with head and neck squamous cell carcinoma (HNSCC), NT219 demonstrated growth inhibition, both as monotherapy (3/6 mice), as well as in combination with cetuximab, an epidermal growth factor receptor (EGFR) inhibitor, or pembrolizumab, a programmed cell death protein 1 (PD-1) inhibitor (5/6 mice). Notably, in one study of a PDX model of a recurrent/metastatic HNSCC sample that was resistant to radiation, various chemotherapies and pembrolizumab, utilizing NT219 alone resulted in tumor growth inhibition (TGI) of 69% (p=0.017). Moreover, while cetuximab alone was not effective (TGI=17%), the combination of cetuximab with NT219 showed synergistic effect and induced regression of all tumors (p=0.001).

"These encouraging preclinical data strongly suggest that the inhibition of the STAT3 and IRS-AKT pathways has the potential to address the tumor resistance phenotype," said Isaac Israel, Chief Executive Officer of Kitov. "Based on the significant compelling preclinical evidence generated in various studies with NT219, including these data, our planned Phase 1/2 trial of NT219 will evaluate our promising product candidate both as a monotherapy treatment in patients with advanced solid tumors and in combination with cetuximab in patients with HNSCC. We look forward to initiating this Phase 1/2 trial soon."

Presentation Details:

Title:	NT219, a novel dual inhibitor of STAT3 and IRS1/2, demonstrates anti-tumor activity with and without cetuximab in pembrolizumab-resistant head and neck cancer PDX models
Date:	June 22, 2020
Abstract:	https://www.abstractsonline.com/pp8/#!/9045/presentation/2911

About Kitov Pharma
Kitov Pharma (Kitov Pharma Ltd.; 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 NT-219 and CM-24. NT-219 is a small molecule targeting the novel cancer drug resistance pathways IRS1/2 and STAT3. Kitov is currently advancing NT-219 in combination with cetuximab as a third-line or second-line treatment option for the treatment of recurrent and metastatic squamous cell carcinoma of head & neck cancer (SCCHN) as well as a single agent monotherapy treatment in patients with advanced solid tumors in a planned Phase 1/2 study. CM-24 is a monoclonal antibody blocking CEACAM1, a novel immune checkpoint that supports tumor immune evasion and survival through multiple pathways. Kitov plans to advance CM-24 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 (BMY) for the planned Phase 1/2 clinical trials to evaluate the combination of CM-24 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 which was approved by the FDA for marketing in the U.S in May 2018, and is expected to be launched in the near future in the U.S. by Kitov's partner 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: different results from the expected benefits, synergies and costs of the acquisition of FameWave by Kitov; management plans relating to the transaction; the plans, strategies and objectives of management for future operations; product development for NT219 and CM-24; the potential future financial impact of the transaction; and any assumptions underlying any of the foregoing; the process by which early stage therapeutic candidates such as NT219 and CM-24 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 lack of sufficient funding to finance the 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 attained by competitors; dependence on the effectiveness of our patents and other protections for innovative products; our ability to obtain, maintain and defend issued patents with protective claims; the commencement of any patent interference or infringement action; 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 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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