Kitov Pharma Announces Significant Progress in Closing of FameWave Acquisition Deal

- Orbimed, Pontifax and Arkin Holdings to deposit $3.5 million investment in Kitov in escrow
- Progress facilitates the advance of activities in development of the oncology asset CM

TEL AVIV, Israel, Aug. 16, 2019 (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 an amendment to the FameWave acquisition deal was signed. According to the amendment, the parties agreed that all major closing conditions have been met other than finalizing the tax ruling for the sellers and the issuance and exchange of shares in the companies. Importantly, the amendment facilitates the advance of activities in the development of the oncology asset CM-24, including the preparation for a Phase 1/2 clinical trial in patients with non-small cell lung cancer in collaboration with Bristol Myers Squibb (BMS). CM-24 is a monoclonal antibody antagonist of CEACAM1, a novel immune checkpoint that supports tumor immune evasion and survival through multiple pathways.

The parties also agreed that Orbimed, Pontifax and Arkin Holdings will deposit in escrow their aggregate $3.5 million investment in Kitov priced at $1.23 per share until the tax ruling is received and the shares are issued and transferred.

"Moving towards finalizing the acquisition of FameWave is an important milestone in Kitov shift towards an oncology focused company. It allows us to advance the clinical development of CM-24 in parallel to advancing our second oncology product NT-219 into clinical trials," said Isaac Israel, chief executive officer of Kitov. "We look forward to initiating the planned Phase 1/2 trial in collaboration with BMS to evaluate the combination of CM-24 with BMS's PD-1 inhibitor Opdivo® in patients with non-small cell lung cancer. CM-24 has the potential to be an effective therapy for cancer patients and we are excited to advance this drug candidate into the clinic soon and provide patients with a long-lasting treatment alternative."

In connection with the progress made toward closing of the acquisition, FameWave has entered into a manufacturing agreement for CM-24 to facilitate the initiation of the Phase 1/2 trial and to advance R&D activities in preparation for the study.

About Kitov Pharma

Kitov Pharma (Kitov Pharma Ltd.; NASDAQ/TASE: KTOV) is a clinical-stage company 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, 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). Kitov is also under contract to acquire 100% of FameWave Ltd. which owns CM-24, a monoclonal antibody blocking CEACAM1, a novel immune checkpoint that supports tumor immune evasion and survival through multiple pathways. Kitov will advance CM-24 as a combination therapy with anti-PD1 checkpoint inhibitors in a clinical collaboration agreement with Bristol Myers Squibb (NYSE:BMY) in a planned Phase 1/2 clinical trials to evaluate the combination of CM-24 with the PD-1 inhibitor nivolumab (Opdivo®) for the treatment of non-small cell lung cancer (NSCLC) All major closing conditions have been met other than finalizing the tax ruling for the sellers and the issuance and exchange of shares in the companies and the acquisition is expected to close during the third quarter of 2019. Consensi, a fixed-dose combination of celecoxib and amlodipine besylate, for the simultaneous treatment of osteoarthritis pain and hypertension was approved by the FDA for marketing in the U.S in May 2018 and is expected to be launched in the U.S. at the end of 2019 by its 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: the manner in which the parties to the transaction for the acquisition of FameWave by Kitov plan to effect the transaction; the expected benefits, synergies and costs of the transaction; management plans relating to the transaction; the expected timing of the completion of the transaction; the parties’ ability to complete the transaction considering the various closing conditions; 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 products such as CM-24 could potentially lead to an approved 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; the uncertainty surrounding an investigation by the Israel Securities Authority into our historical public disclosures which was settled under an administrative enforcement proceeding, and the potential impact of such investigation and settlement on the trading of our securities or on our clinical, commercial and other business relationships, or on receiving the regulatory approvals necessary in order to commercialize our products, and other factors that are discussed in our in our Annual Report on Form 20-F for the year ended December 31, 2018 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.govFor further information, contact:

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