Kitov to Acquire Clinical Stage Candidate CM-24 Creating a Transformational Immuno-Oncology Company

- Transaction adds immune oncology candidate to Kitov's pipeline which includes promising NT-219 cancer drug resistance prevention therapeutic candidate

- Kitov to receive $3.5M investment from prominent life science funds Orbimed, Pontifax, and Arkin Holdings, each becoming a principal shareholder

- Kitov plans to initiate Phase I/II study with CM-24 in early 2020

TEL AVIV, Israel, March 14, 2019 (GLOBE NEWSWIRE) -- Kitov Pharma (NASDAQ/TASE: KTOV), an innovative pharmaceutical company, today announced it has signed an agreement to acquire FameWave Ltd., a privately held biopharmaceutical company developing CM-24, a clinical stage monoclonal antibody targeting CEACAM1, a novel immune checkpoint. Kitov is planning initiation of a Phase I/II study in early 2020 to evaluate the safety and efficacy of CM-24 in combination with an anti PD-1 inhibitor. Kitov to host a conference call to discuss the transaction. The scheduling of the call will be announced separately.

"Combining this transaction with our proprietary NT219 program, Kitov will become a clinical stage oncology company backed by the support of leading global life science funds. With the NT219 and CM-24 oncology candidates, we are opening an exciting future for Kitov and I'm looking forward to building on this momentum. We are very pleased that the investment and support of three leading global life science funds will enable Kitov to advance our clinical programs and expand our institutional investor base," stated Kitov CEO, Isaac Israel.

"The acquisition of CM-24 is a tremendous opportunity for Kitov and our shareholders. We believe CM-24 has the potential to treat recurrent and advanced stage cancers including ovarian, colorectal, melanoma, lung, bladder and gastric cancers, and that our Phase I/II trial design could result in a strong display of the drug's efficacy to the benefit of patients and their families. The journey Kitov started with Consensi™'s FDA approval and our recently announced distribution partnership for Consensi™ in the US, when combined with our plans to submit an IND for NT-219 in 2019 and the acquisition of CM-24, transforms Kitov into a robust immune-oncology development company," Mr. Israel concluded.

Preclinical studies provide strong justification for CM-24's mechanism of action in activating the immune system through multiple pathways as validated by world renowned researchers at Harvard Medical School and MIT, in an article published in Nature* as well as by Prof. Gal Markel from the Tel Hashomer Medical Center**. Additional preclinical studies showed that a combination of CM-24 with a PD-1 antibody resulted in a synergistic anti-cancer effect. Kitov plans to explore higher doses and to test CM-24 in combination with an anti PD-1 inhibitor. A significant amount of data is available for the existing Investigational New Drug (IND) to support the continuation of the clinical studies.

FameWave will enter into a joint clinical collaboration agreement, which is now in an advanced stage of negotiation with a major pharmaceutical company, for a planned Phase I/II study of CM-24 in combination with a PD-1 antibody in early 2020, with preliminary data expected in late 2020.

Acquisition Related Financing

As part of the agreement, three leading life science focused investment funds, Orbimed, Pontifax, and Arkin Holdings, who collectively hold approximately 90% of FameWave, will invest $3.5 million in Kitov in exchange for newly issued ADSs of Kitov, priced at $1.23 per ADS. Following this investment and the FameWave share exchange transaction, Orbimed, Pontifax, and Arkin Holdings will each hold approximately 10% of Kitov's shares on a fully diluted basis.

Kitov is also currently in discussions with a number of leading healthcare-focused institutional investors, which have expressed interest in investing in Kitov following completion of the acquisition.

About the Proposed Transaction

Kitov is acquiring 100% of FameWave from its shareholders in exchange for $10 million worth of its newly issued ADSs with a long term lock-up period, priced at $1.23 per ADS, plus 50% warrant coverage based on an exercise price of $1.98 per ADS with a 4-year term. In addition, Kitov will provide a loan to FameWave of up to approximately $2 million to be paid to cCAM BioTherapeutics Ltd., a wholly owned subsidiary of Merck Sharp and Dohme Corp., known as "MSD" in Israel, which discovered CM-24, or to repay certain loans provided by FameWave's shareholders. In an initial Phase I dose ranging study of CM24 as single agent, no efficacy signals were detected and the decision was made to discontinue development, although such decision was not due to any known safety risks. MSD is therefore returning the rights to CM-24 to former cCAM shareholders and founders of FameWave. Based on a review of the Phase I study results by external scientific advisors retained by Kitov, coupled with their assessment that CM-24 was found to be generally safe, Kitov plans to explore higher doses in order to reach receptor saturation, and test CM-24 in combination with an anti PD-1 inhibitor in a well-defined patient population.

The transaction has been approved by the boards of Kitov and FameWave and is expected to close during the third quarter of 2019, subject to: approval of Kitov shareholders; closing of the transaction for the return of CM-24 to FameWave by MSD; finalization by FameWave of the joint clinical collaboration agreement; and satisfaction of other customary closing conditions. Should the complete transaction not close, Kitov will be entitled to repayment of the amounts loaned by Kitov out of amounts actually received by FameWave from commercialization transactions of CM-24. If no such commercialization transaction is consummated within 36 months from termination, Kitov will be entitled to 20% of FameWave in return for the approximately $2 million loan which was previously provided. Furthermore, should the transaction not close due to the failure of FameWave to finalize the clinical collaboration agreement, or the failure of certain other closing conditions to be fulfilled by the current shareholders of FameWave, then Kitov will be entitled to 100% of FameWave in return for the approximately $2 million loan which was previously provided.

In connection with the proposed acquisition, Kitov intends to file relevant materials with the Securities and Exchange Commission, or the

SEC, including a proxy statement. Investors and security holders of Kitov are urged to read these materials when they become available because they will contain important information about Kitov, FameWave and its shareholders and the proposed acquisition. The proxy statement and other relevant materials (when they become available), and any other documents filed by Kitov with the SEC, may be obtained free of charge at the SEC web site at www.sec.gov. Investors and security holders are urged to read the proxy statement and the other relevant materials when they become available before making any voting decision with respect to the proposed transaction.

This communication does not constitute an offer to sell or the solicitation of an offer to sell or the solicitation of an offer to buy any securities, nor shall there be any sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. The securities of Kitov will be issued to the selling shareholders in FameWave, and to the investors in the investment transaction, on a private placement basis pursuant to applicable exemptions from the prospectus requirements under applicable Israeli securities laws and from the registration requirements of the United States Securities Act of 1933, as amended (the "U.S. Securities Act"). The securities offered have not been registered under the U.S. Securities Act or any U.S. state or Israeli securities laws, and may not be offered or sold in the United States or in Israel, or to, or for the account or benefit of, United States persons or persons in Israel absent registration or any applicable exemption from the registration and/or prospectus requirements of the U.S. Securities Act and applicable U.S. state and/or Israeli securities laws.

About CEACAM1 and CM-24

CM-24 is a humanized monoclonal antibody directed against CEACAM1, an immune checkpoint protein belonging to the Human CEA (Carcino-Embryonic Antigen) protein family. Evidence has shown that CEACAM1 is expressed on tumor infiltrating lymphocytes and is up-regulated in several cancer types. Preclinical studies have shown evidence that CM-24 enhances the cytotoxic activity of tumor-infiltrating lymphocytes (TILs) against various CEACAM1-positive tumor cell lines. CM-24 is being developed for multiple oncological indications according to the expression pattern of its target protein.

About Kitov Pharma

Kitov Pharma (Kitov Pharma Ltd.; NASDAQ/TASE: KTOV) is an innovative pharmaceutical drug development company. Leveraging deep regulatory and clinical-trial expertise, Kitov's veteran team of healthcare and business professionals maintains a proven track record in streamlined end-to-end drug development and approval. Kitov's combination drug, Consensi™, treating osteoarthritis pain and hypertension simultaneously, was approved by the FDA for marketing in the U.S and is partnered in the U.S, China and South Korea. In addition, Kitov's NT219, is a novel patented small molecule designed to overcome cancer drug resistance that is currently in pre-clinical development. By lowering development risk and cost through fast-track regulatory approval of novel late-stage therapeutics, Kitov plans to deliver rapid ROI and long-term potential to investors, while making a meaningful impact on people's lives. For more information on Kitov, the content of which is not part of this press release, please visit http://www.kitovpharma.com.

** Huang Y-H, et al., (2015) Nature, 517(7534): 386–390. doi:10.1038/nature13848*
*** Markel G., et al., (2006) J Immunol., 177:6062-6071; doi: 10.4049/jimmunol.177.9.6062*

Forward-Looking Statements and Kitov's Safe Harbor Statement

Certain statements in this press release are forward-looking statements within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other applicable securities laws. Forward-looking statements can be identified by the use of forward-looking 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 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, including conditions related to Kitov shareholder approvals or FameWave finalizing a clinical trial collaboration agreement; the plans, strategies and objectives of management for future operations of FameWave; product development for CM-24; the potential future financial impact of the transaction; and any assumptions underlying any of the foregoing; 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 and the potential impact of such investigation 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, 2017 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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