Kitov Pharma Reports First Half 2019 Financial Results and Provides Business Update

TEL AVIV, Israel, Aug. 08, 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 financial results for the six-month period ended June 30, 2019.

Key Financial Highlights for the first half of 2019:

- Revenues of $1 million as a result of the first milestone payment from Coeptis Pharmaceuticals.
- Decrease in research and development expenses to $1.7 million compared to $2.8 million in 1H18.
- SG&A expenses of $3.3 million, similar to 1H18.
- Net cash used in operating activities decreased to $2.3 million compared to $3.5 million in 1H18.
- Net cash balance and short-term deposits at the end of 1H19 of $7.8 million, not including $3.5 million investment in Kitov by Orbimed, Pontifax and Arkin expected following completion of the FameWave acquisition.

Isaac Israel, chief executive officer of Kitov Pharma, commented, “During the first half of 2019, we made a great progress in the acquisition of FameWave announced earlier this year, with fulfillment of the major closing conditions including the clinical collaboration agreement signed with BMS. This acquisition of a clinical stage oncology asset is a major step in our shift towards an oncology focused company. With the recent successful completion of the IND-enabling studies to advance NT-219 into the clinic and the almost completed acquisition of CM-24, we will soon initiate clinical trials with both candidates which we believe have a great potential to provide effective and long-lasting treatments for patients.”

Mr. Israel added, “We have additionally achieved significant milestones with Consensi™ during this period. With our plans to launch in the U.S., through our partnership with Coeptis Pharmaceuticals, we are already bringing additional revenues to support our oncology programs. The success of this program is also a reflection of our team’s ability to successfully execute end-to-end development of pharma products.”

Key Research and Development Highlights

NT-219

NT-219 is a first-in-class small molecule dual inhibitor of STAT3 and IRS1/2, with the potential to prevent and overcome drug resistance in various cancer types when used in combination with existing agents. Key achievements for the NT-219 program for the six-month period ended June 30, 2019 include:

- Completed IND-enabling studies to advance NT-219 for the treatment of patients with recurrent or metastatic head and neck cancers.
- Planned Phase 1/2 open label multi-center study which will include a dose escalation with fewer than 20 patients and an expansion cohort with 30 patients, to investigate NT-219 in combination with cetuximab in patients with recurrent and metastatic squamous cell carcinoma of head & neck cancer (SCCHN). The main goal of the study is to evaluate the safety, tolerability and maximum tolerated dose, with a secondary endpoint to obtain preliminary efficacy data.
- Announced new findings related to NT-219 mechanism of action showing that even a short exposure of cancerous cells to NT219 was sufficient to trigger irreversible shutdown of cancer pathways, resulting in a long-term anti-cancer effect. These new findings suggested that IRS1/2 dissociates from the cell membrane, undergoes serine phosphorylation which prevents rebinding to the receptor, and is finally degraded by the proteasome. This sequence of events leads to the blockage of PI3K - AKT pathway – a major cancer cell survival pathway.

CM-24

CM-24 is a clinical-stage monoclonal antibody antagonist of CEACAM1, a novel immune checkpoint that supports tumor immune evasion and survival through multiple pathways. Kitov plans to develop CM-24 as a combination therapy with the PD-1 checkpoint inhibitor nivolumab (Opdivo®) in clinical collaboration with Bristol-Myers-Squibb (BMS) to treat non-small cell lung cancer (NSCLC) patients. Key achievements for the CM-24 program for the six-month period ended June 30, 2019 include:

- Announced signature of agreement to acquire FameWave Ltd., a privately held biopharmaceutical company developing CM-24.
- Announced key milestone in the acquisition of FameWave, with the signature of a clinical collaboration agreement between FameWave and BMS for a Phase 1/2 clinical trials to evaluate the combination of CM-24 with nivolumab (Opdivo®), BMS's PD-1 inhibitor, in NSCLC.
- The safety profile of CM-24 was previously evaluated and found to be well tolerated in a Phase 1 study conducted by Merck at doses up to 10mg/kg. Analysis of the Phase 1 data suggested that CEACAM-1 receptor saturation requires a higher dose of CM-24, which is expected be achieved with less than 20mg/kg if administrated every two weeks. Kitov believes that the combination of CM-24 with Opdivo® is

advantageous over Merck's pembrolizumab (Keytruda®) due to Opdivo®'s Q2W administration protocol, compared to the Q3W administration protocol for Keytruda®.
- FameWave entered into a manufacturing agreement with its contract manufacturer for the production of CM-24 for the planned Phase 1/2 study.

Consensi™

Consensi™ is a fixed-dose combination of celecoxib (Celebrex), a non-steroidal anti-inflammatory drug (NSAID) for the treatment of pain caused by osteoarthritis, and amlodipine besylate (Norvasc), a drug designed to treat hypertension. Consensi™ is under patent protection in the U.S. until 2030 and is the only NSAID whose labeling indicates a reduction of blood pressure and consequent risk reduction of heart attack, stroke, and death. Kitov plans to use revenue from milestone payments from multiple regional licensing deals for Consensi™ to advance its oncology pipeline. Key achievements for the Consensi™ program for the six-month period ended June 30, 2019 include:

- Kitov signed an exclusive marketing and distribution agreement with Coeptis Pharmaceuticals for the U.S. market. The agreement provides for total milestone payments from Coeptis to Kitov of $3.5 million, of which Kitov has already received $1 million upon execution of the agreement. Additional milestone payments are due in the upcoming months upon completion of an agreed manufacturing plan and upon first commercial sales in the U.S. In addition, Kitov will be paid 40%-60% of Coeptis' net profit on Consensi™ sales.

Expected Milestones for 2H19:

- Submit IND for the initiation of Phase 1/2 study with NT-219 in combination with cetuximab in patients with recurrent and metastatic SCCHN.
- Complete closing of transaction for the acquisition of FameWave and its CM-24 candidate
- Complete preparation for launch of Consensi™ in the U.S. with commercial partner Coeptis Pharmaceuticals.
- Submit marketing approval applications to the local regulatory authorities for potential registration of Consensi™ in China which will trigger an additional milestone payment to Kitov.

Financial Results for the Six-Month Period Ended June 30, 2019

- Revenue for the six-month period ended June 30, 2019 was $1 million, resulting from a milestone payment from Coeptis related to Consensi™ in 2019, and same as in the first half of 2018 due to milestone payment from CSBio on Consensi™ in the first half of 2018.
- Research and development expenses for the first half of the year ended June 30, 2019 were $1.7 million, a decrease of $1.1 million compared to the six-month period ended June 30, 2018. The decrease is mainly due to a reduction in clinical trials and regulatory expenses related to Consensi™ prior to its approval by the FDA in the first half of 2018, a decrease in bonuses accrued in the first half of 2018 in connection with FDA approval of Consensi™ as well as a decrease in ESOP costs in the first half of 2019 compared to the first half of 2018.
- Selling, general and administrative expenses for the first half of the year ended June 30, 2019 were $3.3 million, compared to $3.4 million for the first half of year ended June 30, 2018.
- Net cash used in operating activities was $2.3 million for the first half of the year ended June 30, 2019, compared to $3.5 million for the first half of year ended June 30, 2018. The decrease reflects a reduction of operating expenses of $1.2 million in the first half of 2019 compared to first half of 2018.
- Kitov's operating loss for the six-month period ended June 30, 2019 amounted to $3.6 million, compared with an operating loss of $4.4 million for the six-month period ended June 30, 2018. The decrease in operating loss reflects the decrease in operating expenses as mentioned above during 2019.
- Kitov's net loss for the six-month period ended June 30, 2019 amounted to $2.6 million, compared with a net loss of $5.2 million for the six-month period ended June 30, 2018. Basic and diluted loss per share in the first half of 2019 was 14 cents compared to 42 cents in the first half of 2018.
- Cash, cash equivalents and short-term bank deposits totaled $7.8 million as of June 30, 2019. Upon closing of the FameWave acquisition, Kitov will receive an additional $3.5 million investment from Orbimed, Pontifax and Arkin.

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 for the treatment of non-small cell lung cancer (NSCLC). Following the receipt of the approval of Kitov's shareholders for the acquisition of FameWave, and the finalization of a clinical collaboration agreement between FameWave and Bristol Myers Squibb (NYSE:BMY) for their planned Phase 1/2 clinical trials to evaluate the combination of CM-24 with the PD-1 inhibitor nivolumab (Opdivo®), the acquisition is

expected to close during the third quarter of 2019, subject to fulfillment of certain additional closing conditions. 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 or NT-219 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 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, 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.gov For further information, contact:

Gil Efron
Deputy CEO & Chief Financial Officer
+972-3-933-3121 ext. #105

IR@kitovpharma.com

Media Inquiries:
Darren Opland, Ph.D.
darren@lifescipublicrelations.com
+1 646 627 8387

Condensed Consolidated Unaudited Interim Statements of Financial Position as of

	Note	June 30, 2019 USD thousand	December 31, 2018 USD thousand
Assets			
Cash and cash equivalents		**2,757**	5,163
Short term deposits		**5,060**	1,521
Financial asset	**5**	**2,000**	-
Other current assets		**851**	1,830
Total current assets		**10,668**	8,514
Non - current assets			
Right of use assets	**3**	**311**	-
Fixed assets, net		**40**	37
		351	37
Intangible assets		**6,172**	6,172
Total assets		**17,191**	14,723
Liabilities			
Lease liability - short term	**3**	**194**	-
Accounts payable		**861**	705
Other payables		**1,859**	2,055
Derivative liability	**7**	**2,451**	554
Total current liabilities		**5,365**	3,314
Non - current liabilities			
Lease liability		**132**	-
Post-employment benefit liabilities		**256**	405
Total non-current liabilities		**388**	405
Equity			
Share capital, no par value	**6**	-	-
Share premium		**46,945**	44,597
Receipts on account of warrants		**7,940**	7,982
Capital reserve for share-based payments	**8**	**2,448**	1,714
Capital reserve from transactions with related parties		**761**	761
Capital reserve from transactions with non- controlling interest		**(859)**	(859)
Accumulated loss		**(46,247)**	(43,672)
Equity attributable to owners of the Company		**10,988**	10,523
Non-controlling interests		**450**	481
Total equity		**11,438**	11,004
Total liabilities and equity		**17,191**	14,723

Condensed Consolidated Unaudited Interim Statements of Changes in Equity

	Note	For the six months ended June 30	
		2019	**2018**
		USD thousand	**USD thousand**
Revenues	**9**	**1,000**	1,000
Research and development expenses		**1,688**	2,842
General and administrative expenses		**3,305**	3,394
Reimbursement of legal fees		**(430)**	-
Other income, net		**-**	(866)
Total expenses		**4,563**	5,370
Operating loss		**3,563**	4,370
Net change in fair value of derivatives		**(992)**	758
Finance expense		**108**	79
Finance income		**(73)**	(24)
Finance expense (income), net		**(957)**	813
Loss for the period		**2,606**	5,183
Loss attributable to:			
Owners of the Company		**2,575**	4,853
Non-controlling interests		**31**	330
		2,606	5,183
Loss per share			
Basic and diluted loss per share - USD		**0.14**	**0.42
Number of shares used in calculation		**19,183,303**	**12,405,856

** Restated to reflect a 20:1 reverse share split, that took place in January 2019.

Condensed Consolidated Unaudited Interim Statements of Cash Flows

	For the six months ended June 30	
	2019	**2018**
	USD thousand	**USD thousand**
Cash flows from operating activities:		
Loss for the period	**(2,606)**	(5,183)
Adjustments:		
Depreciation	**95**	3
Finance expenses (income), net	**(957)**	813
Share-based payments	**499**	612
Income in regards with settlement with a minority shareholder of a subsidiary	-	(866)
	(2,969)	(4,621)
Changes in assets and liabilities:		
Changes in other current assets	**953**	202
Changes in accounts payables	**142**	525
Changes in other payables	**(226)**	412
Changes in post - employment benefit liabilities	**(170)**	-
	699	1,139
Net cash used in operating activities	**(2,270)**	(3,482)
Cash flows from investing activities:		
Interest received	**30**	24
Increase in short term deposits	**(3,500)**	(3,061)
Investment in Financial asset	**(2,000)**	-
Acquisition of fixed assets	**(8)**	(5)
Net cash used in investing activities	**(5,478)**	(3,042)
Cash flows from financing activities:		
Proceeds from warrants exercised	**43**	515
Proceeds from issuance of shares and ADSs	**2,594**	4,683
Share and ADS issuance expenses paid	**(264)**	(407)
Proceeds from issuance of warrants	**3,406**	3,467
Warrants issuance expenses paid	**(347)**	(301)
Repayment of lease liability	(89)	-
Interest paid	**(14)**	(7)
Net cash provided by financing activities	**5,329**	7,950
Net increase (decrease) in cash and cash equivalents	**(2,419)**	1,426
Cash and cash equivalents at the beginning of the period	**5,163**	3,947
Effect of translation adjustments on cash and cash equivalents	**13**	(10)
Cash and cash equivalents at the end of the period	**2,757**	5,363