# Kitov Pharma Provides Corporate Update and Reports First Half 2020 Financial Results

TEL AVIV, Israel, Aug. 11, 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 provided a corporate update and announced financial results for the six months ended June 30, 2020.

"The first half of 2020 represented a transformative period for Kitov, with multiple commercial, clinical and corporate milestones achieved," said Isaac Israel, Chief Executive Officer. "Importantly, we have successfully completed our evolution to an oncology-focused biotechnology company with the acquisition of CM24, an inhibitor of CEACAM1, and our strong cash balance at the end of the first half of the year of over $60 million positions us well to continue building a pipeline of attractive oncology assets. Moreover, our emerging oncology pipeline continued to advance expeditiously in the first half of the year and we expect to achieve multiple key upcoming catalysts."

"For CM24, we presented positive Phase 1 results at the American Society of Clinical Oncology (ASCO) 2020 Virtual Scientific Program indicating that CM24 at higher doses warrants further evaluation in a larger clinical study, and we look forward to the anticipated initiation of our Phase 1/2 clinical trial to evaluate the combination of CM24 with nivolumab (OPDIVO®), to be conducted in collaboration with Bristol Myers Squibb Company (BMS), in the second half of this year," continued Mr. Israel. "We were excited to receive U.S. Food and Drug Administration (FDA) acceptance of our Investigational New Drug (IND) application to conduct the Phase 1/2 clinical trial that will evaluate NT219 as a monotherapy treatment for advanced solid tumors and in combination with cetuximab for the treatment of recurrent or metastatic solid tumors and head and neck cancer or colorectal adenocarcinoma."

"In addition, we achieved a significant milestone in May 2020 with the U.S. commercial launch of CONSENSI®, a fixed-dose combination of celecoxib and amlodipine besylate, designed for the simultaneous treatment of hypertension and osteoarthritis pain. We believe that our strong balance sheet of $63 million in cash at the end of the first half of 2020, which provides us runway beyond 2024, furnishes us with the financial support for our continued development efforts aimed at further advancing CM24 and NT219, and allows us the flexibility to enhance our growth through potential acquisitions and/or in-licensing activity in our core focus area of oncology," concluded Mr. Israel.

**Recent Corporate Highlights**

**CM24:** a monoclonal antibody targeting CEACAM1, a novel immune checkpoint that supports tumor immune evasion and survival through multiple pathways:

- Presented the positive results of a previously reported Phase 1 trial at the ASCO 2020 Virtual Scientific Program. These encouraging Phase 1 results indicate that CM24 at higher doses warrants further evaluation in a larger clinical study. Importantly, pharmacokinetic (PK) modelling suggests that higher doses of CM24 of up to 20mg/kg administered every two weeks would be required for target saturation.
- Received a notification from the European Patent Office to grant a patent for Kitov's application entitled "Humanized antibodies against CEACAM1," covering protein and DNA sequences pertaining to humanized antibodies capable of specific binding to human CEACAM1 molecules, including its lead monoclonal antibody, CM24, pharmaceutical compositions comprising these antibodies, as well as methods for their use in treating and diagnosing cancer and other conditions.
- Currently advancing preparations to initiate a Phase 1/2 clinical trial of CM24 in combination with nivolumab (OPDIVO®) in patients with non-small cell lung cancer, and in combination with nivolumab in addition to standard of care chemotherapy, in patients with pancreatic cancer. The trial will be conducted under a clinical collaboration agreement with BMS, and is expected to begin in the second half of 2020.

**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:

- Expanded planned Phase 1/2 clinical trial of NT219 with cetuximab trial in patients with recurrent or metastatic head and neck cancer, to also include evaluation of NT219 as monotherapy treatment in patients with advanced solid tumors, based on significant compelling preclinical evidence generated in various studies with NT219.
- Presented promising preclinical data demonstrating the anti-tumor activity of NT219 as both a monotherapy and in combination with cetuximab, an EGFR blocking monoclonal antibody, at the 2020 Multidisciplinary Head and Neck Cancers Symposium.
- Presented preclinical data at the American Association of Cancer Research Virtual Meeting II in a presentation entitled "*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*." Using multiple patient derived xenograft (PDX) models of subjects with head and neck squamous cell carcinoma, NT219 demonstrated growth inhibition, both as monotherapy as well as in combination with cetuximab or pembrolizumab (KEYTRUDA®), a PD-1 inhibitor .
- The FDA accepted Kitov's IND to conduct a Phase 1/2 clinical trial of NT219. The primary objectives of the open-label Phase 1/2 trial are to evaluate safety, assess PK, identify the appropriate dose to be studied in the Phase 2 portion, and establish preliminary efficacy of NT219. We initiated the study in July and expect to activate up to eight sites in the U.S. and Canada over the next few months.

**CONSENSI®**: a fixed-dose combination of celecoxib and amlodipine besylate, designed for the simultaneous treatment of hypertension and osteoarthritis pain:

- Announced the U.S. commercial launch of CONSENSI® by Burke Therapeutics, the marketing partner of Kitov's U.S. distributor, Coeptis Pharmaceuticals. Burke Therapeutics' sales team is growing steadily, and is expected to include approximately 50 sales representatives, with plans to increase this number further.
- According to our agreement with Coeptis for CONSENSI®, Kitov is eligible to receive up to $99.5 million in milestone and reimbursement payments, in addition to royalties.

- Kitov expects to receive aggregate milestone and royalty revenues of between $28 million and $36 million from 2020 through 2022.

**Financing Activities**

- Raised an aggregate of approximately $54.5 million in gross proceeds from registered direct, public offering, and PIPE transactions.
- Received an additional $13.9 million of gross cash proceeds from the exercise of warrants.

**Financial Results for the Six Months Ended June 30, 2020**

*Revenues*
Total revenues for the six months ended June 30, 2020, were $1.0 million, the same as compared to the same period of 2019. The revenue for the six months ended June 30, 2020, included a milestone payment related to the CONSENSI® launch from Coeptis Pharmaceuticals.

*Research & Development (R&D) Expenses*
R&D expenses for the six months ended June 30, 2020, were $3.1 million, an increase of $1.4 million, or 85.6%, compared to $1.7 million in the same period of 2019. The increase was due to preparations related to the anticipated initiation of the CM24 and NT219 clinical trials.

*Selling, General & Administrative (SG&A) Expenses*
SG&A expenses for the six months ended June 30, 2020, were $2.2 million, compared to $3.3 million in the same period of 2019. The decrease was due to a decrease in professional and legal fees, user fees to the FDA and a one-time settlement fee in the first half of 2019.

*Operating Loss*
Operating loss for the six months ended June 30, 2020, was $4.3 million, an increase of $0.6 million, or 20.7%, compared to $3.6 million in the same period of 2019.

On a non-IFRS basis (as reconciled below), adjusted operating loss for the six months ended June 30, 2020, was $3.5 million, an increase of $0.5 million from $3.1 million for the six months ended June 30, 2019.

*Net Loss*
Net loss for the six months ended June 30, 2020, was $27.8 million, or $0.46 per basic and diluted share, compared to a net loss of $2.6 million, or $0.14 per basic and diluted share, in the comparable period of 2019. The increase was due to an increase in expenses related to warrants in the amount of $24.6 million. Adjusted net loss for the first half of 2020 was $3.5 million, compared to $3.1 million in the same period of 2019. The increase of $0.4 million was due to an increase in R&D expenses related to the Company's preparations for the planned initiation of two clinical studies, offset by a decrease in SG&A expenses. .

*Cash & Cash Equivalents*
As of June 30, 2020, we had cash and cash equivalents of $63.0 million, compared to $4.4 million at December 31, 2019. We believe that our cash and cash equivalents will provide sufficient resources for our current ongoing needs through fiscal year 2024.

**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 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 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 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 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 CM-24; 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 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 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.

**Company Contact:**
Gil Efron
Deputy CEO & Chief Financial Officer
IR@kitovpharma.com +972-3-933-3121 ext. #105

Investor Relations Contact:
Chuck Padala
chuck@lifesciadvisors.com
+1 646-627-8390

**Condensed Consolidated Unaudited Interim Statements of Financial Position as of**

| | June 30, 2020 | December 31, 2019 |
|---|---|---|
| | USD thousand | USD thousand |
| **Assets** | | |
| Cash and cash equivalents | **62,995** | 4,385 |
| Short term deposits | **10** | 10 |
| Trade receivables | **1,000** | - |
| Financial asset | **-** | 2,000 |
| Other current assets | 1,555 | 1,907 |
| **Total current assets** | **65,160** | 8,302 |
| | | |
| **Non - current assets** | | |
| Right of use assets | **108** | 206 |
| Fixed assets, net | **33** | 38 |
| | **141** | 37 |
| Intangible assets | **20,482** | 6,172 |
| **Total assets** | **85,783** | 14,718 |
| | | |
| **Liabilities** | | |
| Lease liability - short term | **109** | 195 |
| Accounts payable | **2,965** | 1,245 |
| Other payables | **1,907** | 2,106 |
| Derivative liability | **24,403** | - |
| **Total current liabilities** | **29,384** | 3,546 |
| | | |
| **Non - current liabilities** | | |
| Lease liability | **8** | 28 |
| Post-employment benefit liabilities | **246** | 285 |
| **Total non-current liabilities** | **254** | 313 |
| **Equity** | | |
| Share capital, no par value | - | - |
| Share premium | **103,445** | 46,986 |
| Receipts on account of warrants | **23,001** | 9,874 |
| Capital reserve for share-based payments | **6,697** | 3,181 |
| Capital reserve from transactions with related parties | **761** | 761 |
| Capital reserve from transactions with non- controlling interest | **(859)** | (859) |
| Accumulated loss | **(77,301)** | (49,522) |
| Equity attributable to owners of the Company | **55,744** | 10,421 |

| | | |
|---|---|---|
| Non-controlling interests | **401** | 438 |
| **Total equity** | **56,145** | 10,859 |
| **Total liabilities and equity** | **85,783** | 14,718 |

**Condensed Consolidated Unaudited Interim Statements of Operations**

| | For the six months ended June 30 | |
|---|---|---|
| | **2020** | 2019 |
| | **USD thousand** | USD thousand |
| Revenues | **1,000** | 1,000 |
| Research and development expenses | **3,133** | 1,688 |
| Sales, general and administrative expenses | **2,234** | 3,305 |
| Reimbursement of legal fees | **(65)** | (430) |
| **Total operating expenses** | **5,302** | 4,563 |
| **Operating loss** | **4,302** | 3,563 |
| Expenses (income) on account of warrants | **23,583** | (992) |
| Finance expense | **15** | 108 |
| Finance income | **(84)** | (73) |
| **Finance expense (income), net** | **23,514** | (957) |
| **Loss for the period** | **27,816** | 2,606 |
| **Loss attributable to:** | | |
| Owners of the Company | **27,779** | 2,575 |
| Non-controlling interests | **37** | 31 |
| | **27,816** | 2,606 |
| **Loss per share data** | | |
| Basic and diluted loss per share - USD | **0.46** | 0.14 |
| Number of shares used in calculation of basic and diluted loss per share | 60,091,056 | 19,183,303 |

**Condensed Consolidated Statement of Cash Flows**

| | For the six months ended June 30 | |
|---|---|---|
| | **2020** | **2019** |
| | **USD thousand** | **USD thousand** |
| **Cash flows from operating activities:** | | |
| Loss for the period | **(27,816)** | (2,606) |
| Adjustments: | | |
| Depreciation | **92** | 95 |
| Finance expenses (income), net | **23,514** | (957) |
| Share-based payments | **750** | 499 |
| | **(3,460)** | (2,969) |
| **Changes in assets and liabilities:** | | |
| Changes in other current assets | **(379)** | 953 |
| Changes in accounts payables | **(893)** | 142 |
| Changes in other payables | **130** | (226) |
| Changes in post - employment benefit liabilities | **(39)** | (170) |

| | | |
|---|---|---|
| | **(1,181)** | 699 |
| **Net cash used in operating activities** | **(4,641)** | (2,270) |
| **Cash flows from investing activities:** | | |
| Cash assumed as part of acquisition of FameWave | **69** | - |
| Interest received | **39** | 30 |
| Increase in deposits | **-** | (3,500) |
| Investment in financial asset | **-** | (2,000) |
| Acquisition of fixed assets | **-** | (8) |
| **Net cash provided by (used in) investing activities** | **108** | (5,478) |
| **Cash flows from financing activities:** | | |
| Proceeds from warrants exercised | **13,920** | 43 |
| Proceeds from issuance ADSs | **27,925** | 2,594 |
| ADS issuance expenses paid | **(2,040)** | (264) |
| Proceeds from issuance of warrants | **26,574** | 3,406 |
| Warrants issuance expenses paid | **(3,131)** | (347) |
| Repayment of lease liability | **(80)** | (89) |
| Interest paid | **(11)** | (14) |
| **Net cash provided by financing activities** | **63,157** | 5,329 |
| **Net increase (decrease) in cash and cash equivalents** | **58,624** | (2,419) |
| Cash and cash equivalents at the beginning of the period | **4,385** | 5,163 |
| Effect of translation adjustments on cash and cash equivalents | **(14)** | 13 |
| **Cash and cash equivalents at the end of the period** | **62,995** | 2,757 |
| **Non-Cash activities:** | | |
| **Transfer of derivative instrument from liability to equity** | **10,982** | - |

**Kitov Pharma Reconciliation of Non-IFRS Financial Results**

**Reconciliation of Adjusted Operating Loss**

| | **For the six months ended June 30,** | |
|---|---|---|
| | **2020** | **2019** |
| | **USD thousands** | **USD thousands** |
| Operating loss for the period | **4,302** | 3,563 |
| Less ESOP expenses | **(750)** | (498) |
| | **3,552** | 3,065 |

**Reconciliation of Adjusted Net Loss**

| | **For the six months ended June 30,** | |
|---|---|---|
| | **2020** | **2019** |
| | **USD thousands** | **USD thousands** |
| Net loss for the period | **27,816** | 2,606 |
| Less income (expenses) on account of warrants | **(23,583)** | 992 |
| Less ESOP expenses | **(750)** | (498) |
| | **3,483** | 3,100 |