Kitov Pharma Provides Update on Planned U.S. Launch of ConsensiTM and Provides Three-Year Revenue Forecast

- *Company's marketing partners in the U.S. plan to commence selling Consensi in May 2020*
- *Kitov expects to receive between $28 million and $36 million in milestone and royalty revenues from 2020 through 2022*

TEL AVIV, Israel, March 12, 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 an update on the planned U.S. commercial launch of Consensi™, a fixed-dose combination of celecoxib, and amlodipine besylate, designed for the simultaneous treatment of osteoarthritis pain and hypertension, that was approved for marketing by the U.S. Food & Drug Administration. The Company's manufacturing partner is completing the packaging, release and shipment of Consensi™ to Kitov's marketing partners, that is expected to begin selling Consensi™ in the U.S. in May 2020.

According to the U.S. marketing and distribution agreements, Kitov is eligible to receive up to $99.5 million in milestone, reimbursement payments, and royalties. The Company expects to receive aggregate milestone and royalty revenues of between $28 million and $36 million from 2020 through 2022. The projected revenues will provide an important source of financial support for Kitov as the Company continues to advance its emerging oncology pipeline, including bringing both CM-24 and NT-219 into the clinic this year.

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. CM-24 is a monoclonal antibody blocking CEACAM1, a novel immune checkpoint that supports tumor immune evasion and survival through multiple pathways. Kitov intends to advance CM-24 as a combination therapy with anti-PD1 checkpoint inhibitors for the treatment of non-small cell lung cancer (NSCLC). Kitov has entered into a clinical collaboration agreement with Bristol Myers Squibb (NYSE: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 U.S. in May 2020. 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.

About Consensi™

Consensi is a fixed-dose combination of amlodipine besylate, a calcium channel blocker for the treatment of hypertension, to lower blood pressure, and celecoxib, a nonsteroidal anti-inflammatory drug (NSAID) for the management of the signs and symptoms of osteoarthritis. The U.S. Food & Drug Administration (FDA) approved Consensi oral tablets for marketing and Kitov is partnered in the U.S, China and South Korea.

For additional information see DailyMed, Full Prescribing Information, including BOXED WARNING and Medication Guide.

Important Safety Information (ISI) for Consensi®

WARNING: RISK OF SERIOUS CARDIOVASCULAR and GASTROINTESTINAL EVENTS

See full prescribing information for complete boxed warning.

CONSENSI contains celecoxib, a nonsteroidal anti-inflammatory drug (NSAID), and amlodipine, a calcium channel blocker (CCB). NSAIDs can cause serious side effects, including:

- **Increased risk of a heart attack or stroke that can lead to death. This risk may happen early in treatment and may increase with duration of use.**
- **Do not take CONSENSI right before or after a heart surgery called a "coronary artery bypass graft" (CABG).**
- **Avoid taking CONSENSI after a recent heart attack, unless your healthcare provider tells you to. You may have an increased risk of another heart attack if you take NSAIDs after a recent heart attack.**
- **NSAID medications, like celecoxib, cause an increased risk of bleeding, ulcers, and tears (perforation) of the esophagus, stomach, and intestines, at any time during treatment, which can occur without warning and may**

cause death. Elderly patients and patients with a prior history of peptic ulcer disease and/or GI bleeding are at greater risk for serious GI events.

What is the most important information I should know about Consensi?

Consensi contains celecoxib, a nonsteroidal anti-inflammatory drug (NSAID), and amlodipine, a calcium channel blocker (CCB). NSAIDs can cause serious side effects, including:

- **Increased risk of a heart attack or stroke that can lead to death.** This risk may happen early in treatment and may increase:

  - with increasing doses of NSAIDs
  - with longer use of NSAIDs

Do not take Consensi right before or after a heart surgery called a "coronary artery bypass graft" (CABG).

Avoid taking Consensi after a recent heart attack, unless your healthcare provider tells you to. You may have an increased risk of another heart attack if you take NSAIDs after a recent heart attack.

- **Increased risk of bleeding, ulcers, and tears (perforation) of the esophagus (tube leading from the mouth to the stomach), stomach, and intestines:**

  - anytime during use
  - without warning symptoms
  - that may cause death

The risk of getting an ulcer or bleeding increases with:

- past history of stomach ulcers, or stomach or intestinal bleeding with use of NSAIDs
- taking medicines called "corticosteroids", "antiplatelet drugs", "anticoagulants", "selective serotonin reuptake inhibitors (SSRIs)", or "serotonin norepinephrine reuptake inhibitors (SNRIs)"
- increasing doses of NSAIDs
- longer use of NSAIDs
- smoking
- drinking alcohol
- older age
- poor health
- advanced liver disease
- bleeding problems

You should not take other medicines that contain NSAIDs or salicylates during treatment with Consensi because of increased risk of stomach problems. Taking other medicines that contain NSAIDs or salicylates during treatment with Consensi will not provide increased relief of symptoms of osteoarthritis.

Consensi should only be used:

- exactly as prescribed
- at the lowest dose possible for your treatment
- for the shortest time needed

Who should not take Consensi?

Do not take Consensi:

- if you are allergic to amlodipine, celecoxib or any of the inactive ingredients in Consensi.
- if you have had an asthma attack, hives, or other allergic reaction with aspirin or any other NSAIDs.
- right before or after heart bypass surgery.
- if you have had an allergic reaction to sulfonamides.

Before taking Consensi, tell your healthcare provider about all your medical conditions, including if you:

- have heart problems.

- have liver or kidney problems.
- have asthma.
- are pregnant or plan to become pregnant. Talk to your healthcare provider if you are considering taking Consensi during pregnancy. **You should not take Consensi after 29 weeks of pregnancy.**
- are breastfeeding or plan to breastfeed. Consensi can pass into your breast milk. It is not known if Consensi will harm your baby. Talk with your healthcare provider about the best way to feed your baby if you take Consensi.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, or herbal supplements. Consensi® and some other medicines can interact with each other and cause serious side effects. **Do not start taking any new medicine without talking to your healthcare provider first.**

What are the possible side effects of Consensi?

Consensi can cause serious side effects, including:

- liver problems, including liver failure
- worsening chest pain (angina) or heart attack, particularly in people with severe obstructive coronary artery disease
- heart failure
- swelling of your arms, legs, hands and feet (peripheral edema) is common with Consensi but can sometimes be serious.
- kidney problems, including kidney failure
- increased potassium levels (hyperkalemia)
- life-threatening allergic reactions
- life-threatening skin reactions
- low red blood cells (anemia)

See "What is the most important information I should know about Consensi?" for further detail regarding serious side effects.

Your healthcare provider will monitor your blood pressure and do blood tests to check you for side effects during treatment with Consensi.

Consensi may cause fertility problems in females that is reversible when treatment with Consensi is stopped. Talk to your healthcare provider if this is a concern for you.

The most common side effects of Consensi include:

- swelling of the arms, legs, hands, and feet
- joint swelling
- dizziness
- stomach pain
- diarrhea
- heartburn
- headache
- frequent urination
- hot or warm feeling in your face (flushing)
- gas
- tiredness
- extreme sleepiness

Get emergency help right away if you get any of the following symptoms:

- shortness of breath or trouble breathing
- chest pain
- weakness in one part or side of your body
- slurred speech
- swelling of the face or throat

Stop taking Consensi and call your healthcare provider right away if you get any of the following symptoms:

- nausea
- more tired or weaker than usual
- diarrhea
- itching
- indigestion or stomach pain
- flu-like symptoms
- vomit blood
- there is blood in your bowel movement or it is black and sticky like tar
- unusual weight gain
- your skin or eyes look yellow
- skin rash or blisters with fever
- swelling of the arms, legs, hands and feet

These are not all the possible side effects of Consensi.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or **www.fda.gov/medwatch**. You may also report side effects to Burke Therapeutics, LLC at 1-866-275-1264.

Please see Full Prescribing Information, including BOXED WARNING, and Medication Guide**.**

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: our ability to successfully develop and commercialize our pharmaceutical products; 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, 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

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