

---

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM 6-K

**Report of Foreign Private Issuer  
Pursuant to Rule 13a-16 or 15d-16  
of the Securities Exchange Act of 1934**

For the month of May 2018

Commission File Number: 001-37643

**KITOV PHARMA LTD.**  
(Translation of registrant's name into English)

**One Azrieli Center, Round Tower,  
132 Menachem Begin Road, Tel Aviv 6701101, Israel**  
(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F.

Form 20-F  Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

---

---

Kitov Pharma Ltd. (the “Company” or the “Registrant”) is announcing that U.S. Food and Drug Administration (FDA) has approved Consensi™ (amlodipine and celecoxib) oral tablets for marketing. On May 31, 2018, the Company issued a press release in connection with the FDA approval, “**FDA Approves Kitov’s Consensi™ for Treatment of Osteoarthritis Pain and Hypertension**”, which is attached hereto as Exhibit 99.1.

Exhibit 99.1 [Press Release](#)

This Form 6-K is incorporated by reference into each of the Registrant’s Registration Statements on Form F-3 filed with the Securities and Exchange Commission on December 12, 2016 (Registration file numbers 333-207117, 333-211477 and 333-215037), the Registrant’s Registration Statement on Form S-8 filed with the Securities and Exchange Commission on May 20, 2016 (Registration file number 333-211478), and the Registrant’s Registration Statement on Form S-8 filed with the Securities and Exchange Commission on June 6, 2017 (Registration file number 333-218538).

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**KITOV PHARMA LTD.**

May 31, 2018

By: /s/ Isaac Israel  
Isaac Israel  
CEO & Director

## FDA Approves Kitov's Consensi™ for Treatment of Osteoarthritis Pain and Hypertension

New drug choice for millions of Americans offers one pill for treatment of osteoarthritis pain with a built-in antihypertensive

TEL AVIV, Israel, May 31, 2018 / GlobeNewswire/ --

Kitov Pharma Ltd. (NASDAQ: KTOV; TASE: KTOV), an innovative biopharmaceutical company, announced today that the U.S. Food and Drug Administration (FDA) has approved Consensi™ (amlodipine and celecoxib) oral tablets for marketing.

Consensti™ is a patent-protected combination of celecoxib, a non-steroidal anti-inflammatory drug (NSAID), and amlodipine besylate, an antihypertensive calcium channel blocker. Consensi™ was approved for once daily use in three dosage forms, corresponding to the current approved dosages of amlodipine (2.5, 5, and 10 mg) for hypertension and a 200 mg dose of celecoxib for the treatment of osteoarthritis pain.

"We are very pleased with Consensi™'s approval and would like to thank the members of Kitov's team, consultants and investigators, as well as the FDA's Division of Cardiovascular and Renal Products, for all of their support and assistance," said Dr. J. Paul Waymack, Chairman of Kitov's Board and Chief Medical Officer. "Consensti™ provides a safe and effective combination treatment option for the millions of Americans who suffer from osteoarthritis pain and hypertension.

"Now that Consensi™ has been approved for marketing, our clinical and regulatory teams will focus on leveraging their drug development expertise to advance NT219, an exciting investigational new drug candidate currently in development for various oncology indications."

Isaac Israel, Kitov's CEO, added: "This approval demonstrates the Kitov team's ability and experience in expertly guiding Consensi™ through clinical trials and regulatory review, from Investigational New Drug (IND) submission to FDA approval in less than four years.

"Over 50 million Americans suffer from osteoarthritis. About 1 of 3 U.S. adults or about 75 million people have high blood pressure\*, known as the "silent killer" due to the absence of noticeable symptoms. As a result, patients' adherence to the hypertension treatment regimen is low. We believe that Consensi™, as a single pill combination treatment for osteoarthritis and hypertension, presents a unique value proposition of potentially increasing treatment adherence.

"We recently expanded our commercialization network for Consensi™ by securing a second licensing agreement in Asia with a major Chinese pharmaceutical company. The FDA approval of Consensi™ puts us in a stronger position towards securing commercial partnerships for the U.S. and other key territories."

The FDA-approved Consensi™ New Drug Application included the positive results from the Company's Phase III clinical trial. These data demonstrated that the study met its primary endpoint of showing that the drug lowers daytime systolic blood pressure by at least 50% of the reduction in blood pressure achieved in patients treated with amlodipine besylate only, with statistical significance of  $p=0.001$ . Kitov also submitted the positive results from its randomized double-blind, placebo-controlled renal function Phase III/IV clinical trial of Consensi™. Data from this study validated the primary efficacy endpoint achieved in the completed Phase III clinical trial. This study also demonstrated that treatment with Consensi™ led to a statistically significant reduction of serum creatinine, a marker of renal function, from its baseline value ( $p=0.0005$ ), demonstrating improved renal function in patients treated with the combination. In contrast, neither amlodipine besylate nor placebo lowered creatinine to a statistically significant level.

---

\* According to the US Centers for Disease Control and Prevention (<https://www.cdc.gov/bloodpressure/index.htm>)

---

## **About Consensi™**

Full US Prescribing Information, including BOXED WARNING and Medication Guide is available at: [www.consenzi.com](http://www.consenzi.com).

### Indications and Usage:

Consenzi™ is a combination of amlodipine besylate, a calcium channel blocker, and celecoxib, a nonsteroidal anti-inflammatory drug (NSAID), indicated for patients for whom treatment with amlodipine for hypertension and celecoxib for osteoarthritis are appropriate. Lowering blood pressure reduces the risk of fatal and nonfatal CV events, primarily strokes and myocardial infarctions.

### Limitations of Use:

Consenzi™ is only available in a celecoxib strength of 200 mg and is only to be taken once daily.

### **Important Safety Information (ISI) for Consensi™**

The following ISI is based on the Highlights section of the U.S. Prescribing Information for Consensi™. Please consult the full Prescribing Information for all of the labelled safety information for Consensi™.

**Nonsteroidal anti-inflammatory drugs (NSAIDs) cause an increased risk of serious cardiovascular (CV) thrombotic events, including myocardial infarction and stroke, which can be fatal. This risk may occur early in the treatment and may increase with duration of use.**

**Consenzi™ is contraindicated in the setting of coronary artery bypass graft (CABG) surgery.**

**NSAIDs cause an increased risk of serious gastrointestinal (GI) adverse events, including bleeding, ulceration and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients and patients with a prior history of peptic ulcer disease and/or GI bleeding are at greater risk for serious GI events.**

Consenzi™ is contraindicated in patients with a known hypersensitivity to amlodipine, celecoxib or any of its inactive ingredients.

Consenzi™ is contraindicated in patients with a known history of asthma, urticaria or other allergic-type reactions after taking aspirin or other NSAIDs and in the setting of CABG surgery.

Consensi<sup>TM</sup> is contraindicated in patients with known demonstrated allergic-type reactions to sulfonamides.

Significant warnings and precautions related to Consensi<sup>TM</sup> include the following:

Patients should be warned about the potential signs and symptoms of hepatotoxicity and hepatic failure. Physicians should discontinue Consensi<sup>TM</sup> if abnormal liver tests persist or worsen, or if clinical signs and symptoms of liver disease develop.

Patients taking some antihypertensive medications may have impaired response to these therapies when taking NSAIDs. Physicians should carefully monitor blood pressure.

Symptomatic hypotension is possible, particularly in patients with severe aortic stenosis.

Worsening angina and acute myocardial infarction, particularly in patients with severe obstructive coronary artery disease, is possible.

Physicians should avoid use of Consensi<sup>TM</sup> in patients with severe heart failure.

Physicians should monitor renal function in patients with renal or hepatic impairment, heart failure, dehydration, or hypovolemia, and avoid the use of Consensi<sup>TM</sup> in patients with advanced renal disease.

Patients should seek emergency help if an anaphylactic reaction occurs.

Consensi<sup>TM</sup> is contraindicated in patients with aspirin-sensitive asthma. Monitor patients with preexisting asthma (without aspirin sensitivity).

Physicians should discontinue Consensi<sup>TM</sup> at the first appearance of skin rash or other signs of hypersensitivity.

NSAIDs such as Consensi<sup>TM</sup> can cause premature Closure of Fetal Ductus Arteriosus.

Avoid use in pregnant women starting at 30 weeks of gestation.

Physicians should monitor hemoglobin or hematocrit in patients with any signs or symptoms of anemia.

Consensi<sup>TM</sup> is not recommended in patients with moderate or severe hepatic impairment or severe renal insufficiency.

Consensi<sup>TM</sup> is not recommended in Poor Metabolizers of CYP2C9 Substrates.

To report SUSPECTED ADVERSE REACTIONS, contact Kitov Pharma at 1-800-651-6606 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch)

## **About Kitov Pharma**

Kitov Pharma (Kitov Pharma Ltd.; NASDAQ/TASE: KTOV) is an innovative biopharmaceutical drug development group of companies. 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 flagship combination drug, Consensi™, intended to treat osteoarthritis pain and hypertension simultaneously, achieved the primary efficacy endpoints for its Phase III and Phase III/IV clinical trials, and was approved by the FDA for patients suffering from osteoarthritis pain and hypertension. NT219, which is developed by its majority-owned subsidiary, TyrNovo Ltd., 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>.

## **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 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>

## **For further information, contact:**

Simcha Rock  
Chief Financial Officer  
+972-3-933-3121 ext. #105  
[simcha@kitovpharma.com](mailto:simcha@kitovpharma.com)

Bob Yedid  
Managing Director  
LifeSci Advisors, LLC  
+1-646-597-6989  
[bob@lifesciadvisors.com](mailto:bob@lifesciadvisors.com)