## 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 February 2020

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)

(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 on February 24, 2020, the Company issued a press release, "Kitov Pharma Expands Planned NT-219 Clinical Program for Difficult to Treat Cancers", which is attached hereto as Exhibit 99.1.

#### Exhibit 99.1 Press Release

This Form 6-K, including all exhibits hereto, is hereby 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 and 333-211477), 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), 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), the Registrant's Registration Statement on Form F-3, as amended, originally filed with the Securities and Exchange Commission on July 16, 2018 (Registration file number 333-226195), the Registrant's Registration Statement on Form S-8 filed with the Securities and Exchange Commission on March 28, 2019 (Registration file number 333-230584), the Registrant's Registration Statement on Form F-3 filed with the Securities and Exchange Commission on September 16, 2019 (Registration file number 333-233795) and the Registrant's Registration Statement on Form F-3 filed with the Securities and Exchange Commission on December 2, 2019 (Registration file number 333-235327), to be a part thereof from the date on which this report is submitted, to the extent not superseded by documents or reports subsequently filed or furnished.

# 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.

February 24, 2020 By: /s/ Isaac Israel

Isaac Israel CEO & Director

#### Kitov Pharma Expands Planned NT-219 Clinical Program for Difficult to Treat Cancers

Phase 1/2 Study to Evaluate NT-219 as Monotherapy Treatment of Advanced Solid Tumors, as well as in Combination with cetuximab for Treatment of Recurrent or Metastatic Solid Tumors and Head and Neck Cancer

Company to Present Details of Planned Phase 1/2 Trial and Preclinical Data Demonstrating Anti-tumor Activity of NT-219 in Poster at 2020 Multidisciplinary Head and Neck Cancers Symposium

TEL AVIV, Israel, Feb. 24, 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 announced it will expand the planned Phase 1/2 clinical trial of NT-219 with cetuximab trial in patients with recurrent or metastatic head and neck cancer, to also include evaluation of NT-219 as monotherapy treatment in patients with advanced solid tumors. Kitov expects to initiate this study in the second quarter of 2020, pending clearance of its Investigational New Drug application by the U.S. Food and Drug Administration. NT-219 is a small molecule dual inhibitor of IRS1/2 and STAT3, pathways associated with treatment resistance.

The details of the planned Phase 1/2 trial will be presented in a poster at the 2020 Multidisciplinary Head and Neck Cancers Symposium, which is being held in Scottsdale, Arizona, from February 27-29, 2020. The presentation will include details of the Phase 1/2 study, as well as new preclinical data demonstrating the anti-tumor activity of NT-219 as both a monotherapy and in combination with cetuximab, an epithelial growth factor receptor (EGFR) blocking monoclonal antibody.

"Our strategic decision to expand our planned clinical study to evaluate NT-219 as monotherapy is based on the significant compelling preclinical evidence generated in various studies with NT-219, including the data we will be presenting this week," said Isaac Israel, chief executive officer of Kitov. "The promising preclinical data demonstrate the anti-cancer potential of NT-219, both as a monotherapy and in combination with cetuximab, anti-PD1 inhibitors and other agents. We expect that the establishment of standalone safety data and potential efficacy will provide a solid foundation for further evaluation of NT-219 in a number of different clinical settings. We look forward to advancing NT-219 into the clinic in the second quarter of this year."

The Phase 1/2 study will be an open-label, dose escalation and subsequent expansion phase study. The study will have a dose escalation component of NT-219 as a single agent; a dose escalation phase of NT-219 in combination with cetuximab; and an expansion phase of NT-219 at its recommended Phase 2 level in combination with a standard dose of cetuximab. Advanced solid tumors, as well as recurrent or metastatic squamous cell carcinoma of the head and neck, will be evaluated. Other possible expansion cohorts will be determined based on the Phase 1 dose escalation and further preclinical data.

The primary objectives of the study will be to assess plasma pharmacokinetics, safety, tolerability and maximum tolerated dose of NT219 as a single agent, and in combination with cetuximab. The secondary objectives will be to assess pharmacokinetics and efficacy of different dose levels of NT219, alone and in combination with cetuximab.

Presentation details are as follows:

**Abstract Title:** A Phase 1/2, Open-Label, Dose Escalation Followed by Single-Arm Expansion to Assess the Safety and Efficacy of NT219 in Combination with Cetuximab in Patients with Recurrent/Metastatic (R/M) Head and Neck Squamous Cell Carcinoma (HNSCC)

**Date**: February 27-29, 2020 **Presentation number**: 312

**Session**: Poster **Location**: Exhibit Hall

The poster will also be available for download from February 27, 2020 at: http://kitovpharma.investorroom.com/index.php?s=151

#### **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 will 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<sup>TM</sup>, 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. during 2020 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: 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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