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 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)

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 May 22, 2020, the Company issued a press release, "**Kitov Announces U.S. FDA Acceptance of Investigational New Drug Application to Conduct Phase 1/2 Clinical Trial of NT219 in Multiple Types of Advanced Cancer Patients**", which is attached hereto as Exhibit 99.1.

Exhibit 99.1 Press Release

This Form 6-K, including all exhibits attached 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), 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), the Registrant's Registration Statement on Form F-3 filed with the Securities and Exchange Commission on May 13, 2020 (Registration file number 333- 238229), and the Registrant's Registration Statement on Form S-8 filed with the Securities and Exchange Commission on May 28, 2020 (Registration file number 333-238481), 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.

May 22, 2020

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

Exhibit 99.1

Kitov Announces U.S. FDA Acceptance of Investigational New Drug Application to Conduct Phase 1/2 Clinical Trial of NT219 in Multiple Types of Advanced Cancer Patients

Company to Evaluate NT219 as Monotherapy Treatment of Advanced Solid Tumors and in Combination with Cetuximab for Treatment of Recurrent or Metastatic Solid Tumors and Head and Neck Cancer in a Phase 1/2 Trial

TEL AVIV, Israel, May 22, 2020 -- 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 that the U.S. Food and Drug Administration (FDA) has accepted its Investigational New Drug (IND) application to conduct a Phase 1/2 clinical trial of NT219, a novel agent addressing treatment resistance in advanced cancer. The study will evaluate NT219 as monotherapy treatment of advanced solid tumors and in combination with cetuximab, an epithelial growth factor receptor (EGFR) blocking monoclonal antibody, for the treatment of recurrent or metastatic solid tumors and head and neck cancer or colorectal adenocarcinoma.

"The acceptance of our IND by the FDA to conduct this important clinical study represents a significant achievement for our NT219 development program," said Bertrand Liang, M.D., Ph.D., Chief Medical Officer of Kitov. "Based on the encouraging preclinical data generated in various studies with NT219, we believe this promising drug candidate has the potential to be a safe and effective therapy for multiple treatment resistant cancers. We look forward to beginning to generate key clinical evidence for NT219 through this Phase 1/2 trial."

The primary objectives of the open-label Phase 1/2 trial are to evaluate safety, assess pharmacokinetics, identify the appropriate dose to be studied in the Phase 2 portion, and establish preliminary efficacy of NT219. The Phase 1 portion of the study will encompass a dose escalation evaluation of NT219 monotherapy administered weekly in patients with refractory advanced solid tumors. Upon reaching the third dose to be given, a second cohort of patients, with either recurrent or metastatic squamous cell carcinoma of the head and neck or colorectal adenocarcinoma, will be dosed weekly with NT219, dose escalated, in combination with cetuximab. Upon completion of the mono and combination therapy Phase 1 portion of the trial and establishment of the recommended Phase 2 dose for NT219, an expansion Phase 2 component of the study will be commenced at the recommended Phase 2 dose of NT219 in combination with cetuximab in patients with recurrent/metastatic squamous cell carcinoma of the head and neck.

In previously completed preclinical studies, NT219 has demonstrated compelling anti-tumor activity, as both monotherapy and in combination with cetuximab. Most recently, in an abstract published at the American Association of Cancer Research Virtual Meeting II website, positive preclinical data were presented showing that NT219 demonstrated growth inhibition, both as monotherapy, as well as in combination with cetuximab or pembrolizumab, a programmed cell death protein 1 (PD-1) inhibitor, in multiple patient-derived xenograft models of subjects with head and neck squamous cell carcinoma.

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: different results from the expected benefit and synergies 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, 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.

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