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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 April 2019

Commission File Number: 001-37643

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

**One Azrieli Center, Round Tower,  
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): \_\_\_\_

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Kitov Pharma Ltd. (the “Company” or the “Registrant”) is announcing that in connection with a previously announced conference call to be held on **Monday, April 15, 2019, at 8:30 a.m. EDT** to discuss the FameWave acquisition deal and new asset CM-24, the conference call presentation is attached hereto as Exhibit 99.1

Exhibit 99.1     [Kitov Pharma Investors Call Presentation – April 2019](#)

## 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.

April 15, 2019

**KITOV PHARMA LTD.**

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



## CM-24: A Novel Immune Checkpoint Inhibitor

Investors Call - April 2019



## Forward-Looking Statements and Kitov's Safe Harbor Statement

Certain statements in this presentation 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. Examples of forward-looking statements include, among others, statements we make regarding: (i) the therapeutic and commercial potential of CM-24; (ii) research and development plans related to the CM-24 therapies; (iii) the potential of CM-24 for the treatment of against various CEACAM1-positive tumor cell lines; (iv) the potential for the collaboration between Kitov (FameWave) and Bristol Myers Squibb; and (v) the closing of the transactions between the shareholders of FameWave and Kitov, which is subject to closing conditions, including approval of the transactions by Kitov shareholders. 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 manner in which the parties to the transaction for the acquisition of FameWave by Kitov plan to effect the transaction; the expected benefits, synergies and costs of the transaction; management plans relating to the transaction; the expected timing of the completion of the transaction; the parties' ability to complete the transaction considering the various closing conditions, including conditions related to Kitov shareholder approvals; the plans, strategies and objectives of management for future operations; product development for CM-24; the potential future financial impact of the transaction; and any assumptions underlying any of the foregoing; the process by which early stage products such as CM-24 could potentially lead to an approved 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; 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, 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>



## CM-24 Opportunity

- Monoclonal Ab targeting CEACAM1, a novel immune checkpoint with high potential to treat multiple oncology indications
- CM-24 was well tolerated in a Phase 1 study in doses up to 10mg/kg
- Only clinical stage therapeutic candidate currently targeting CEACAM1
- Plan to develop in a clinical collaboration with Bristol Myers-Squibb for Phase 1/2 trial in combination with nivolumab (Opdivo®) in non-small cell lung cancer (NSCLC)
- Kitov to acquire all rights to CM-24
- Program is supported by new investment from blue-chip investors - Orbimed, Pontifax and Arkin Holdings

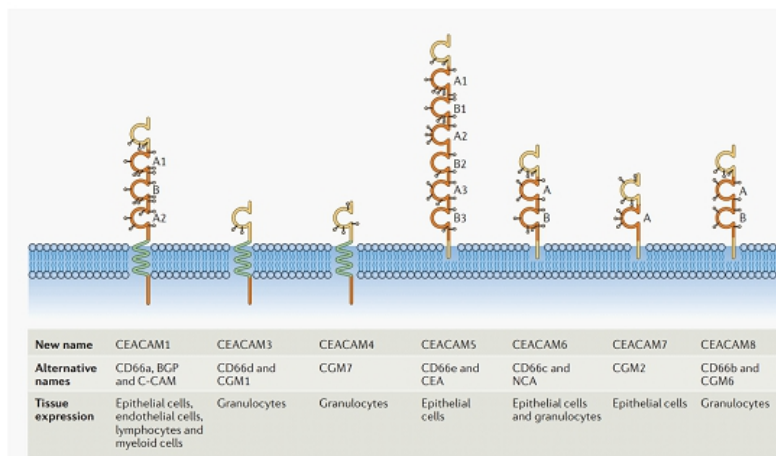


**OrbiMed**  
Healthcare Fund Management

**PONTIFAX**

**ARKIN HOLDINGS**

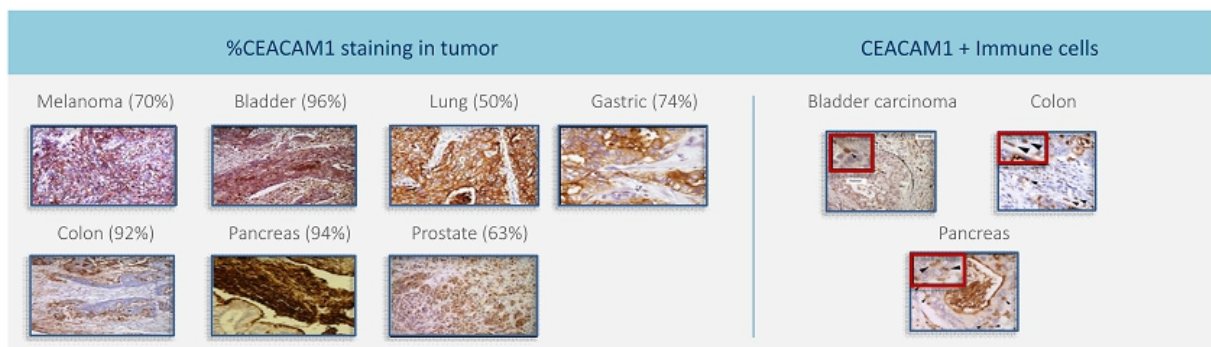
# CEACAM1 is a Member of the Human CEA Family (Carcinoembryonic Antigen Cell Adhesion Molecule)



- Known to interact with both CEACAM1 and CEACAM5
- Also known to interact with TIM3
- Only member expressed on lymphocytes
- Modulator of T-cell function and activity at the tumor site
- Conceptually, analogous to PD-1/PDL-1

Gray-Owen and Blumberg, CEACAM1: contact-dependent control of immunity, *Nature Review Immunology*, 2006, DOI: <https://doi.org/10.1038/nri1864>

# CEACAM1 is Expressed in Both Tumor and Tumor-infiltrating Immune Cells



CEACAM1 staining with MGR1 (murine version of CM-24) on various tissue microarrays from different cancer types



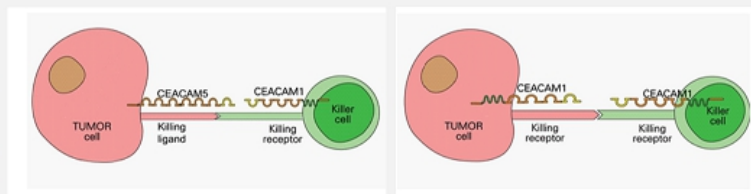


## CM-24 - Mechanism of Action

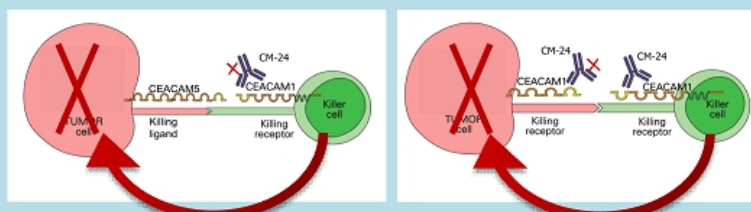
Conceptually, analogous to PD-1/PDL-1

CM24 blocks CEACAM1/1 and CEACAM1/5 interactions evoking anti tumor immune response

**(Tumor) CEACAM1/5 – (T-cell) CEACAM1 interaction prevents killing of tumor cells** through: a) inhibition of the immune activity of TILs, b) lowering phosphorylation of immunoreceptors, and c) reduction of the phosphorylation level of ZAP70 in T cells

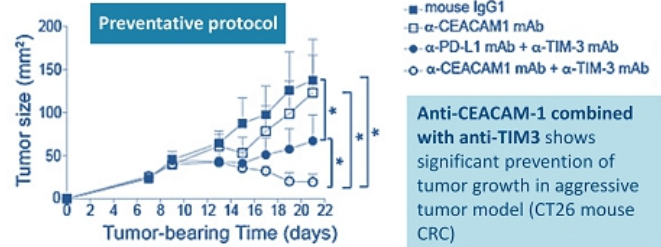
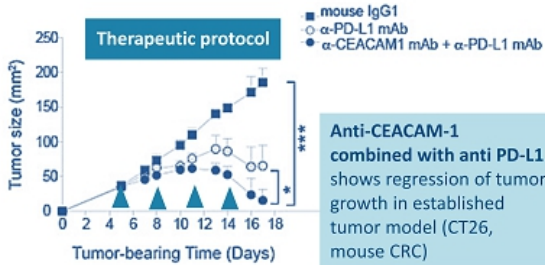


**Blockage of CEACAM1-CEACAM1/5 interaction by CM24 enables cytotoxic activity of lymphocytes and killing of tumor cells by T and NK cells**



## CM-24 - Mechanism of Action (cont.)

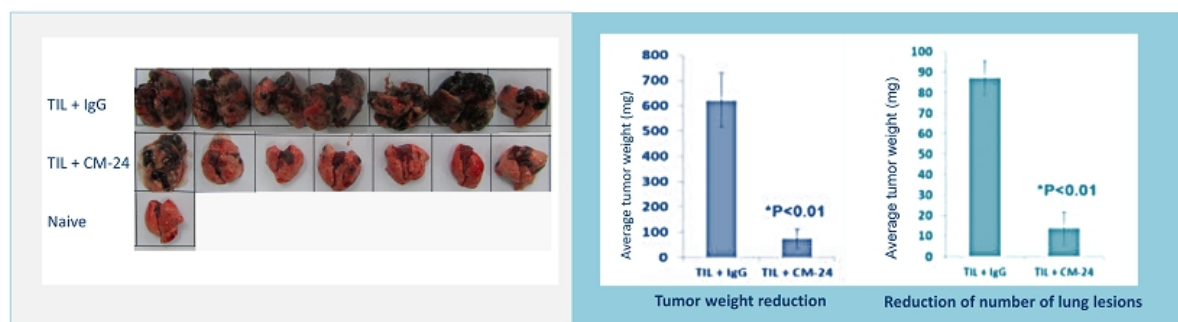
By blocking CEACAM-1 heterodimerization with TIM-3, immune exhaustion of T-cells is abrogated, allowing cooperative tumor inhibition



Huang et al, CEACAM1 regulates TIM-3-mediated tolerance and exhaustion; Nature, 2015 DOI: <https://doi.org/10.1038/nature13848>

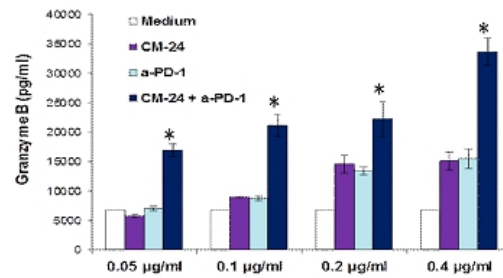
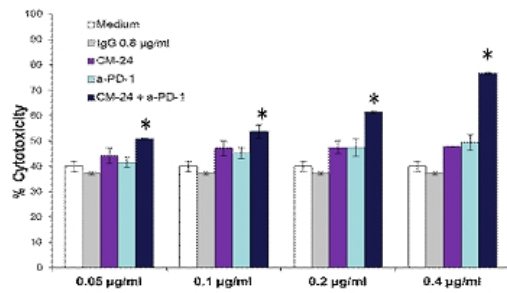
GSK (Tesaro) and Novartis have initiated clinical studies targeting TIM3, noting the relevance of this target in the maintenance of the tumorigenic phenotype, with high potential CEACAM-1 + TIM3 combination therapies

# Sustained Inhibition Of Lung Tumor Growth Following Treatment with CM-24 + TIL



- Xenograft, lung lesion melanoma model
- Tumor burden was monitored 26 days post last CM-24 treatment

# Synergistic Anti-Cancer Effect Following Treatment with CM-24 + Anti PD-1



Combination index (CI) = 0.15

$$CI = \frac{(D)_1}{(D_x)_1} + \frac{(D)_2}{(D_x)_2} < 1 \rightarrow \text{synergism}$$



## Phase 1 CM-24 Trial Data

- Open-label, multi-dose escalation study to assess the **safety and tolerability** of CM-24 as a **monotherapy** and in **combination** with pembrolizumab (Keytruda®)\*
- Conducted by Merck in 4 centers (US: UCLA, Yale; Israel: Sheba, Ichilov)

### 27 patients:

Colorectal	11
Melanoma	7
Ovarian	4
Gastric	3
NSCLC	2

### Dose #pt

0.01mg/kg	1
0.03mg/kg	1
0.1 mg/kg	3
0.3 mg/kg	3
1.0 mg/kg	3
3.0 mg/kg	9
10.0 mg/kg	7



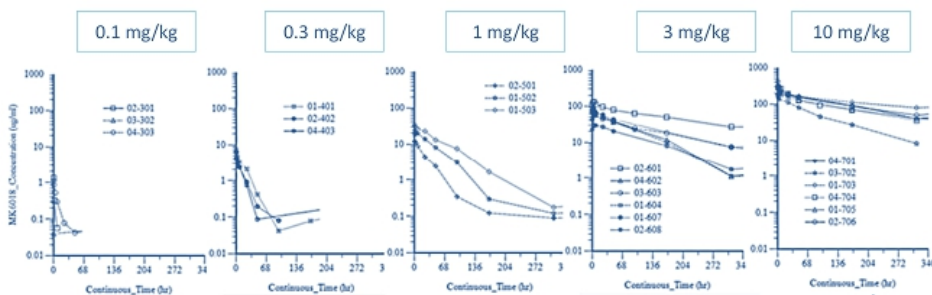
- |   |  |
|---|--|
| <ul style="list-style-type: none"> <li>No DLTs up to 10 mg/kg</li> <li>Drug-related AEs were observed in 63% of the subjects</li> <li>Grade 3-5 occurred in 3.7% of the patients</li> </ul> | <ul style="list-style-type: none"> <li>No discontinuation of study drug due to an AE</li> <li>No drug related mortalities</li> <li>Overall, treatment with CM-24 was well tolerated</li> </ul> |
|---|--|

\* Combination with keytruda® was not clinically tested



## Phase 1 CM-24 Trial Data

Saturation Was Not Reached With Doses Up to 10mg/Kg



Slower clearance with increasing dose

Higher half-life with increasing dose

Merck's conclusion: Saturation likely requires > 10 mg/kg



## Moving Forward With CM-24

- CM-24 has a good safety and tolerability profile
- CM-24 +  $\alpha$ PD-1 antibody combination demonstrated synergistic anti-cancer effect
  - Opdivo® is a good candidate for a combination therapy replicating the Opdivo®/Yervoy® success
  - Dosing level based on PK - start at 8mg/kg and escalate to predicted saturation levels
  - CEACAM1 expression in tumor specimens will be measured
- Significant amount of data for the IND package, including safety and PK, is available to support additional clinical studies
- Clinical collaboration with Bristol Myers-Squibb for next Phase 1/2 trial to evaluate CM-24 in combination with nivolumab (Opdivo®) in subjects with non-small cell lung cancer:
  - BMS to collaborate with Kitov on designing the study protocol, including BMS supplying Opdivo®
  - Estimated cost ~\$10-13M



## Upcoming Milestones (Post CM-24 Transaction)

Milestone	Expected Date
CM-24 - Shareholders approval of the transaction	Q2:19
NT-219 - Complete pre-clinical development plan	H1:19
CM-24 - Closing of the transaction	Q3:19
NT-219 - Submit IND application to FDA	H2:19
NT-219 - Initiation of a clinical study	H2:19
Consensi™ - Complete preparation for U.S. launch	H2:19
CM-24 - IND amendment	H1:20
CM-24 - Initiation of a clinical study in collaboration with Bristol Myers-Squibb	H1:20





## Company Overview (Post CM-24 Transaction)

Kitov Pharma is advancing first-in-class combination oncology therapies to overcome tumor drug resistance, increase treatment response rate, and slow tumor progression



### DIVERSE PIPELINE ADDRESSING LARGE MARKETS

- NT-219 - small molecule designed to overcome cancer drug resistance
- CM-24 - a novel immune checkpoint with high potential to treat multiple oncology indications
- Consensi™ - approved by FDA to treat osteoarthritic pain and hypertension, licensed for marketing in the U.S., China and S. Korea



### PROVEN TEAM AND STRONG PARTNERS

- Management team with proven track record in drug development, NDA submissions and FDA approvals
- Consensi™ manufacturing and CMC by Dexcel Pharma, to be distributed in the U.S. by Coepris Pharmaceutical's experienced team
- CM-24 clinical collaboration with Bristol Myers-Squibb



### COMPELLING VALUE

- Publicly traded on TASE 2013; IPO on NASDAQ in November 2015
- Tickers: KTOV (ADSs); KTOVW (Warrants)
- Cash on hand (as of January 2019): ~\$13M + \$3.5M of investment pending closing of CM-24 transaction
- Market Cap: ~\$38M\*
- ~35% of the shares held by blue-chip, institutional healthcare focused investors

\* As of April 12<sup>th</sup>, 2019, including CM-24 transaction and investment shares



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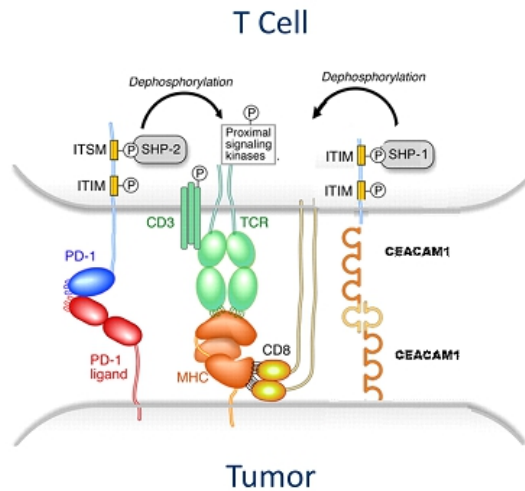


# EXHIBITS

# Human CEACAM1 is a Modulator of T cell Function



- Human CEACAM1 is a modulator of T-cell function
- CEACAM1 expression up-regulated on
  - Activated T and NK cells
  - Various cancer cells
- CEACAM1(tumor) and CEACAM1 (T-cell) interaction prevents killing of tumor cell
- CEACAM-1 inhibition also noted to remove immune exhaustion by heterodimerization with TIM-3, creating multiple MOA
- Conceptually, analogous to PD-1/PDL-1
- Predominantly modulation of T cell activity at the tumor site



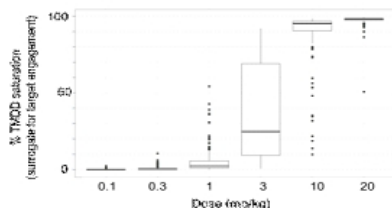
*Adapted and modified from Freeman G J PNAS 2008*



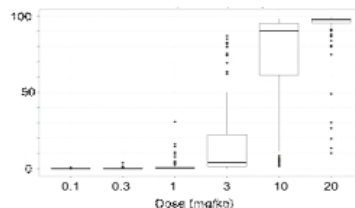
## Saturation Was Not Reached With Doses Up to 10mg/Kg (cont.)

2-compartment PK model including TMDD was performed by Merck. Model was simulated to characterize TMDD saturation:

Simulated TMDD saturation at Ctrough with Q2W regimen



Predictions with Q3W regimen (not clinically tested)



- Consistent with observed PK showing high clearance at doses <10 mg/kg, plot shows low TMDD saturation at low doses
- 10 mg/kg approaches > 90% saturation but >10 mg/kg dose is needed for saturation across population
- Keytruda®'s administration regimen is Q3W
- With Q3W, 10 mg/kg is predicted to achieve only > 50% saturation

Bristol Myers-Squibb's Opdivo® administration regimen is Q2W, thus CM-24's saturation is expected to be better than in combination with Keytruda®

# Inhibition of Melanoma Growth Following CM-24 and CM24 + TIL Treatment



CM-24 activity is demonstrated as single agent and in combination with TILs

