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 October 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): ____

Kitov Pharma Ltd. (the "Company" or the "Registrant") is announcing that it has made available an updated Company Presentation on its website. A copy of the updated Company Presentation is attached hereto as Exhibit 99.1 and may be viewed at the Company's website at www.kitovpharma.com.

Exhibit 99.1	Kitov Pharma Company Presentation – October 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.

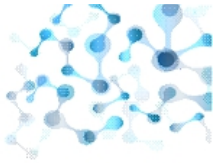
KITOV PHARMA LTD.

October 18, 2019

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

Exhibit 99.1

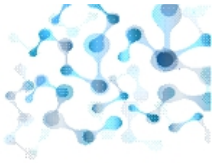
Forward-Looking Statements and Safe Harbor



This presentation is not a prospectus or offer of securities for subscription or sale in any jurisdiction.

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. 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 acquire, develop or 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 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.

Kitov Pharma



A clinical-stage company advancing first-in-class oncology therapies

CM-24 – Inhibitor of CEACAM1

NT-219 – Dual inhibitor of IRS 1/2 and STAT3

- NASDAQ/TASE:KTOV
  - 33% of shares held by healthcare focused investors* including Orbimed Advisors, Pontifax
  - Market Cap: $22M* ($0.74/ADS)
  - 6-month average trading volume: 265K shares
- $8M Cash on hand (as of June 30, 2019)
  - Additional $3.5M following CM-24 transaction closing by year end
  - $7.5M minimum revenues from Consensi™ in next 3 years

From Development Through FDA Approval to Commercialization

* As of October 15th, 2019, including CM-24 transaction and investment shares

Experienced Leadership

Eric K. Rowinsky, MD
Chairman of the Board
Formerly CMO at ImClone, Stemline,
Board member at Biogen Inc.

Bertrand Liang, MD, PhD, MBA, AMP
Medical Director Oncology
Formerly at Biogen Idec, Amgen, NCI

Isaac Israel
Chief Executive Officer
Formerly CEO of BeeContact Ltd. (TASE:BCNT),
NextGen Biomed (TASE: NXGN)

Hadas Reuveni, Ph.D.
Vice President, Research and Development
Formerly at Keryx (NASDAQ:KERX)

Gil Efron
Deputy CEO and Chief Financial Officer
Formerly CFO at Kamada (NASDAQ:KMDA)

Gil Ben-Menachem, Ph.D., MBA
Vice President, Business Development
Formerly at Teva, Dexcel, NIH

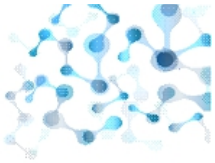
Biogen · TEVA · National Institutes of Health · KAMADA · Stemline · KERYX · NIH National Cancer Institute · AMGEN

From Development to Commercialization

Program	Indication	Preclinical	Phase 1	Phase 2	Phase 3	Partners	Value Drivers
CM-24	Non-Small Cell Lung Cancer (combination with nivolumab)					Bristol-Myers Squibb	Study initiation H2:20 Phase 1 data H1:21
NT-219	Head and Neck Cancer (combination with cetuximab)						Study initiation Q1:20 Phase 1 data H1:21

Product	Indication	Status	Partners	Value Drivers
Consensi™	Simultaneous treatment of osteoarthritic pain and hypertension	Approved for marketing by U.S. FDA on May 31, 2018	U.S.: Coeptis Pharmaceuticals China: CSBio S. Korea: Kuhnil Pharmaceutical	U.S. Launch: Q1:20

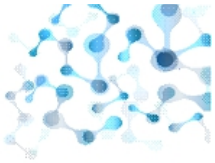
Targeting indications with substantial unmet need



Advancing first-in-class Oncology Therapies

CM-24 – Inhibitor of CEACAM1

CM-24 Immune checkpoint inhibitor



Targets a Novel Immune Checkpoint

- First-in-class mAb blocking CEACAM1
- Conceptually analogous to anti-PD(L)1

Demonstrated Efficacy in Preclinical Models

- Enhances anti-tumor immune activity through multiple pathways
- Demonstrated sunergy with anti- PD(L)1

Well Tolerated in a Clinical Trial

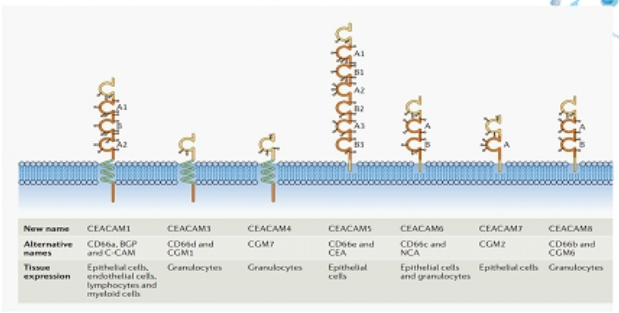
- Studied as a monotherapy in a phase 1
- Doses up to 10 mg/kg

Phase 1/2 Trial to start in 2020

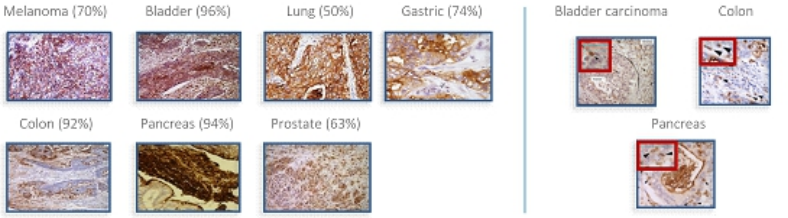
- In combination with nivolumab (Opdivo®) in NSCLC
- Starting at dose of 8mg/kg

CEACAM1 Plays a pivotal role in the immune system

- CEACAM1 (Carcinoembryonic Antigen Cell Adhesion Molecule 1) - member of the Human CEA Family
- Conceptually, analogous to PD-1/PDL-1
- Interacts with both CEACAM1 and CEACAM5
- Regulates TIM-3-mediated tolerance and exhaustion*
- High expression in tumor and in tumor-infiltrating immune cells



New name	CEACAM1	CEACAM3	CEACAM4	CEACAM5	CEACAM6	CEACAM7	CEACAM8
Alternative names	CD66a, BGP and C-CAM	CD66d and CGM1	CGM7	CD66e and CEA	CD66c and NCA	CGM2	CD66b and CGM6
Tissue expression	Epithelial cells, endothelial cells, lymphocytes and myeloid cells	Granulocytes	Granulocytes	Epithelial cells	Epithelial cells and granulocytes	Epithelial cells	Granulocytes

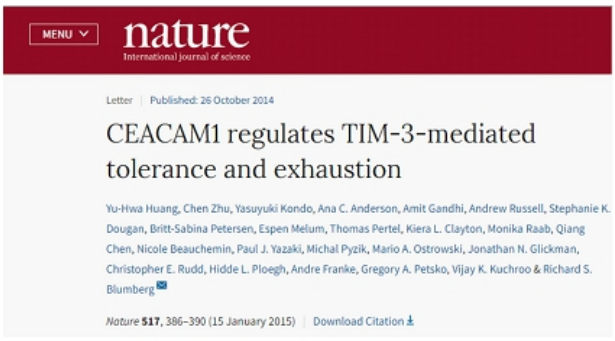


*Gray-Owen and Blumberg, CEACAM1: contact-dependent control of immunity, Nature Review Immunology , 2006, DOI: https://doi.org/10.1038/nri1864

CEACAM1 and TIM-3

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

- TIM-3 is co-expressed and forms a heterodimer with CEACAM1
- The presence of CEACAM1 endows TIM-3 with inhibitory function
- CEACAM1-deficient T cells are hyper-inflammatory with reduced cell surface expression of TIM-3
- Anti-CEACAM-1 combined with anti-TIM3 showed significant prevention of tumor growth in aggressive tumor model (CT26 mouse CRC)


MENU nature
International Journal of science

Letter | Published: 26 October 2014

CEACAM1 regulates TIM-3-mediated tolerance and exhaustion

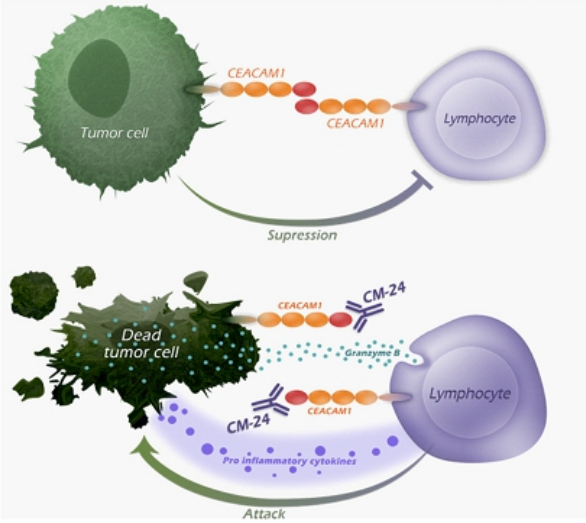
Yu-Hwa Huang, Chen Zhu, Yasuyuki Kondo, Ana C. Anderson, Amit Gandhi, Andrew Russell, Stephanie K. Dougan, Britt-Sabina Petersen, Espen Melum, Thomas Pertel, Kiera L. Clayton, Monika Raab, Qiang Chen, Nicole Beauchemin, Paul J. Yazaki, Michal Pyzik, Mario A. Ostrowski, Jonathan N. Glickman, Christopher E. Rudd, Hidde L. Ploegh, Andre Franke, Gregory A. Petsko, Vijay K. Kuchroo & Richard S. Blumberg

Nature **517**, 386–390 (15 January 2015) | Download Citation

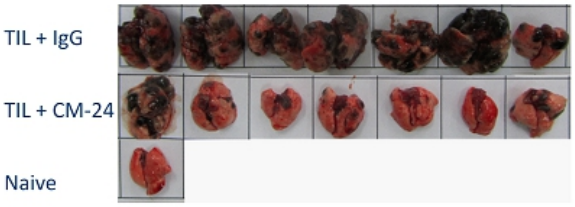
CEACAM-1 + TIM3 combination introduces an innovative approach to TIM-3 regulation

CM-24 MOA: Blocks CEACAM1-mediated interactions

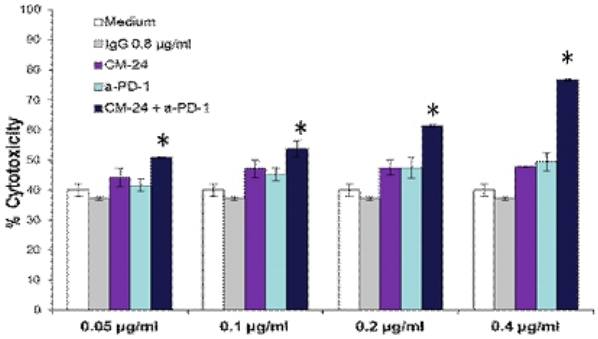
- CM-24 is a humanized IgG4 mAb highly specific to the extracellular domain of CEACAM1 with Nano-molar affinity
- CM-24 prevents CEACAM1-CEACAM1 or CEACAM1-CEACAM5 interaction, thus enhancing the cytotoxic activity of the lymphocytes



Anti-Cancer Effect Following Treatment with CM-24 + TIL and CM-24 + Anti-PD1



- Xenograft, lung lesion, Mel 526 (IV)
- Tumor burden was monitored 26 days post last CM-24 treatment

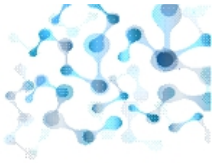


Combination index (CI) = 0.15

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

Significant benefits as both single agent and in combination

CM-24 Phase 1 Monotherapy Trial



- Open-label, multi-dose escalation study to assess **safety and tolerability** of CM-24
- Conducted by Merck in 4 centers US: UCLA, Yale; Israel: Sheba, Sourasky
- Heavily pre-treated patients with a median of 3 prior regimens (range 2-7) and a median of 4 prior regimens at the 3mg/kg & 10mg/kg doses

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 mg/kg	3
3 mg/kg	9
10 mg/kg	7

q2wks x4 → 6 weeks observation only

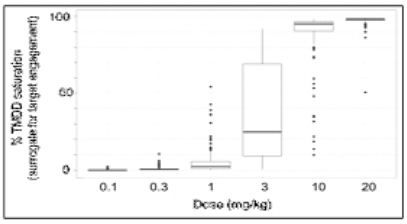
✓ No DLTs up to 10 mg/kg ✓ No discontinuation of study drug due to an AE ✓ No drug related mortalities ✓ 29.6% SD (RECIST)

Overall, treatment with CM-24 was well tolerated

Merck Concluded that Saturation Likely Requires > 10mg/kg

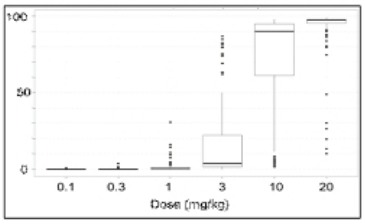
Merck models simulated to characterize TMDD saturation

Simulated TMDD saturation at Ctrough with Q2W regimen



- 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

Predictions with Q3W regimen (not clinically tested)



- Keytruda®'s administration regimen is Q3W
- With Q3W, 10 mg/kg is predicted to achieve only > 50% saturation

The simulation suggests CM-24 administered Q2W (similar to BMS' Opdivo®) is expected to saturate the target with dosing at 20 mg/kg

Market opportunity: Non-Small Cell Lung Cancer

Rationale for combining Opdivo® + CM-24

- Preclinical data supports significant synergistic benefit
- Receptor saturation with CM-24 is better achieved with a Q2W regimen and is aligned with the Opdivo® protocol
- Collaboration with Bristol-Myers Squibb, a leader in immuno-Oncology (I/O) research, to address an urgent need

Targeting the unmet medical need

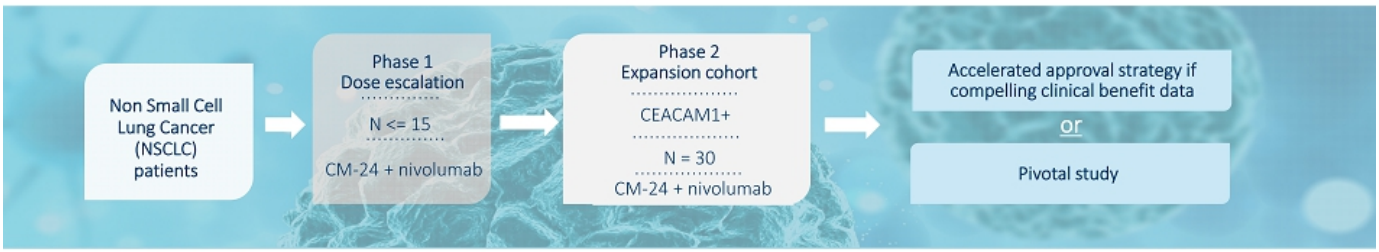
- Non-small cell lung cancer accounts for 85% of all lung cancer diagnoses, approx. 193,927 new cases/year; with a 5-year relative survival rate of 23%*
- Immunotherapy is now recommended as second line therapy in all patients with NSCLC and no driver mutations**
- 5-year overall survival rates with chemotherapy in 2L is 2.6% and with I/O Opdivo® is 13.4%***

**American Cancer Society, Cancer Facts & Figures 2019, and the ACS website*
***Economopoulou P, Mountzios G. The emerging treatment landscape of advanced non-small cell lung cancer. Ann Transl Med. 2018;6(8):138. doi:10.21037/atm.2017.11.07*
**** Gettinger S, et al "Five-year outcomes from the randomized, phase III trials CheckMate 017/057: Nivolumab vs docetaxel in previously treated NSCLC" WCLC 2019; Abstract OA14.04.*

Opdivo® + CM-24 has the potential to provide long lasting effective treatment

CM-24 Accelerated Biomarker-driven Clinical Development

1. In a clinical collaboration with Bristol Myers-Squibb
   - A Phase 1/2 open label multi center study of CM-24 in combination with nivolumab (Opdivo®) in NSCLC
     1. Dose escalation starting at 8mg/kg
     2. Expansion cohort
   - **Primary endpoint**: Evaluate the safety, pharmacokinetics and to-determine the MTD
   - **Secondary endpoint**: Obtain preliminary efficacy data
   - Measurement of CEACAM1 expression levels to identify a potential correlative biomarker

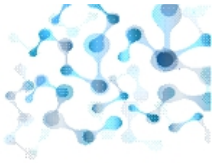


2. Exploring further studies in other tumor types as well as monotherapy

Advancing first-in-class oncology therapies

NT219 – Dual inhibitor of IRS 1/2 and STAT3

NT-219 Drug Resistance Prevention



Unique MoA

- Inhibits two key resistance signaling proteins: IRS1/2 and STAT3

Efficacious in Multiple PDX Models

- Prevents, delay and reverses resistance to anti-cancer drugs in Head and Neck, Colon, Lung, and Pancreatic cancers models

Enhances Every Treatment Regimen

- In combination with immuno-oncology, targeted and chemo therapies

Phase 1/2 to Start in Q1:2020

- First-in-human clinical trial in SCC of the Head and Neck cancer in combination with cetuximab (Erbitux®)

IRS1/2 and STAT3 Role in Cancer Drug Resistance

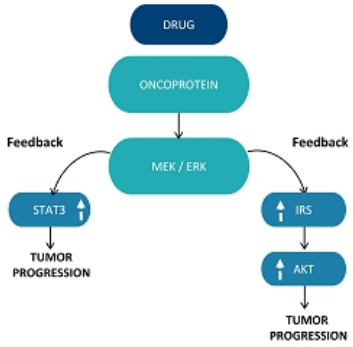
IRS1/2

- Part of the IGFR complex
- Phosphorylated on tyrosine residues and triggers activation of PI3K/AKT and MEK/ERK signaling pathways
- Regulates cell proliferation, protein synthesis, survival, gene expression and apoptosis

STAT3

- Active in the JAK/STAT3 immune evasion mechanism of the tumor
- Provides a crucial axis to support cell proliferation and survival

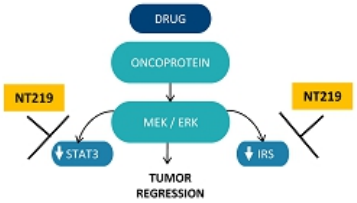
Drug resistance



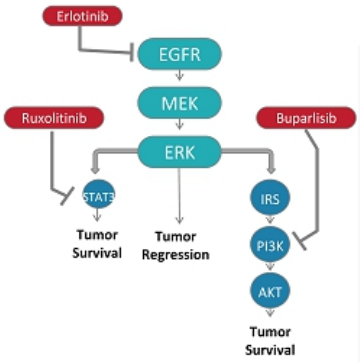
IRS1/2 and STAT3 are key signal transducers activated as a feedback response to anti-cancer drugs, leading to drug resistance

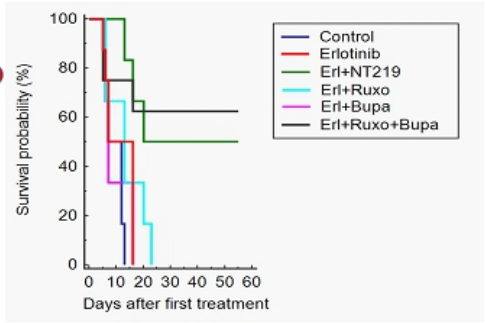
NT-219 MOA: Inhibition of Both STAT3 and IRS is Required to Overcome Resistance

Overcoming drug resistance



PDX of H&N cancer: modeling overcoming drug resistance

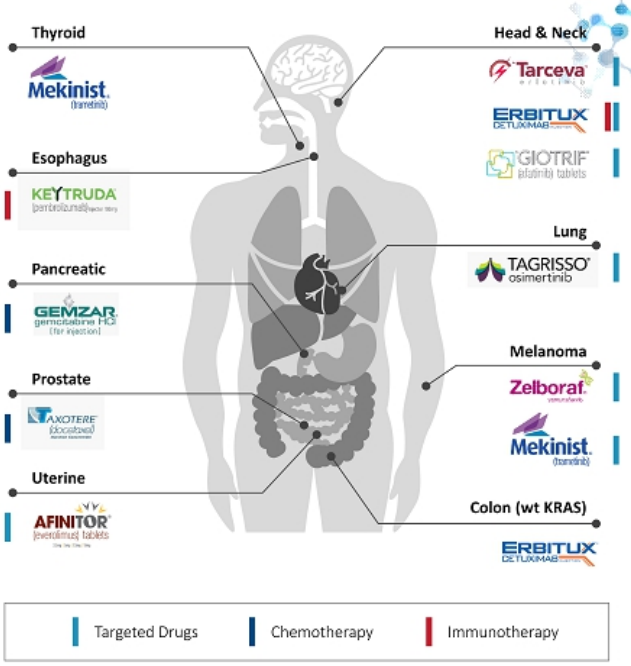




By blocking <u>both</u> STAT3 and IRS resistance pathways, NT-219 prevents tumor resistance and re-sensitizes tumors to anti-cancer therapies

Efficacy Demonstrated in Combination with Multiple Drug Classes in Preclinical Models

- Increased efficacy
- Expanded target population
- Extended treatment duration



Targeted Drugs | Chemotherapy | Immunotherapy

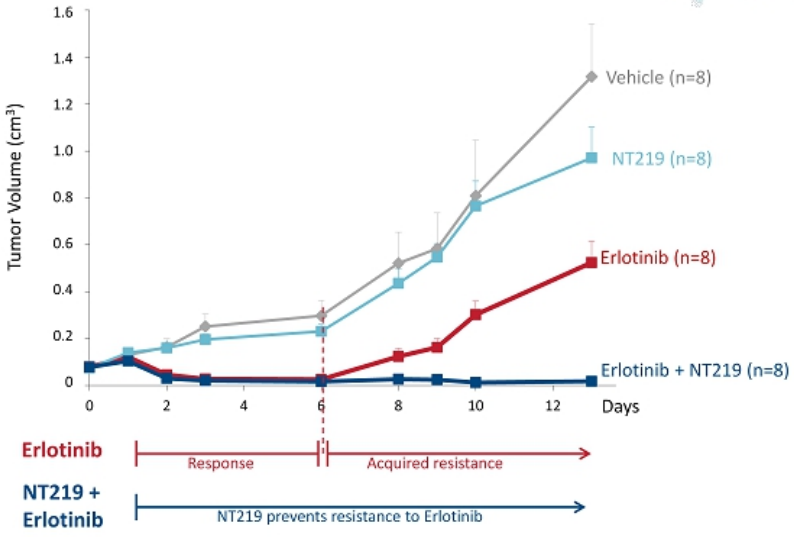
NT219 Prevents Acquired Resistance to Erlotinib

PDX model

Head & Neck Cancer

Drugs

Erlotinib (Tarceva®)



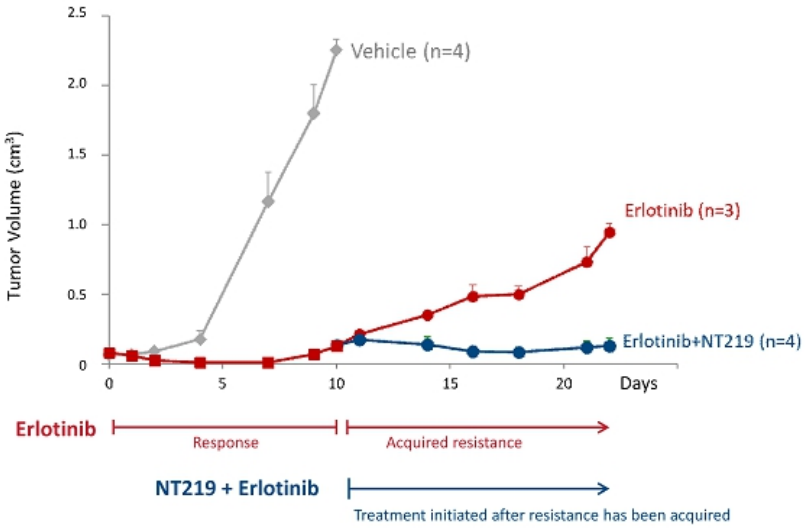
NT219 Reverses Erlotinib-acquired Resistance

PDX model

Head & Neck Cancer

Drugs

Erlotinib (Tarceva®)



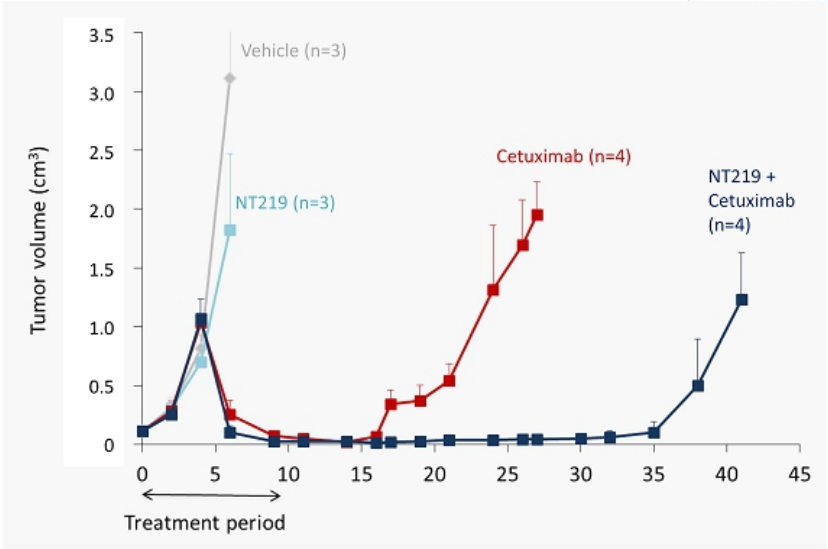
NT219 Delays Tumor Recurrence

PDX model

Head & Neck Cancer

Drug

Cetuximab (Erbitux®)



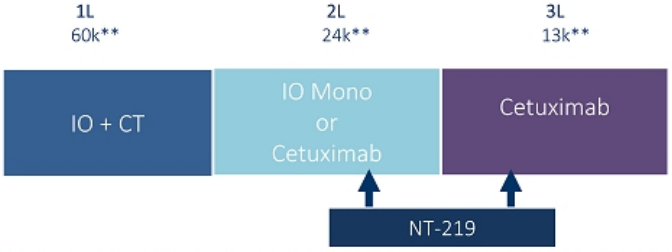
Market Opportunity: Recurrent or Metastatic Squamous Cell Carcinoma of Head and Neck (SCCHN)

Rationale for combining Cetuximab + NT-219

- EGFR and PD(L)-1 are the only clinically validated targets in SCCHN
- Cetuximab inhibits EGFR signaling and promotes ADCC
- STAT3 and IRS-to-AKT activation contributes to resistance to cetuximab in HNSCC

Targeting the unmet medical need

- 1L Standard of care is shifting from chemotherapy towards immuno-oncology + chemotherapy*
- Only < 20% of R/M SCCHN patients respond to anti-PD1s
- Number of new cases/year is expected to be 174,000 by 2024



* Global Data 2018: Head and Neck Squamous Cell Carcinoma: Opportunity Analysis and Forecasts to 2026
** Internal best current estimates of patient numbers based on external research, 5 major global territories

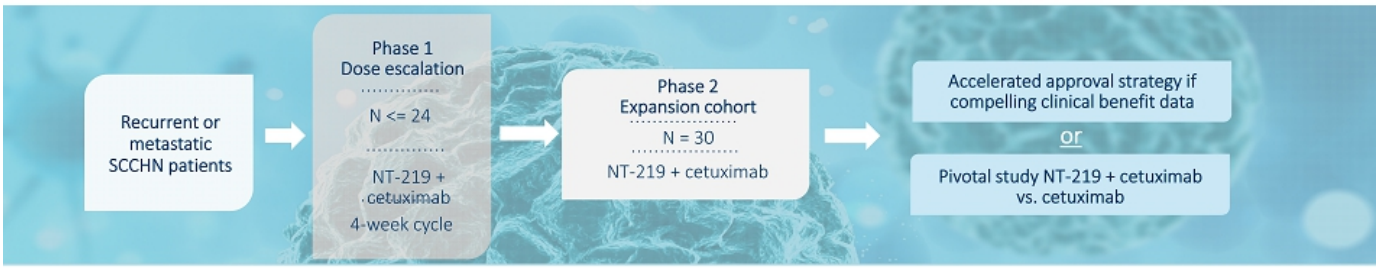
NT-219 + cetuximab has the potential to become an attractive 2-3L therapy

NT-219 Clinical Development Plan

1. A Phase 1/2 open label multi center study of NT-219 in combination with cetuximab in patients with recurrent or metastatic SCCHN

1. Dose escalation
2. Expansion cohort

- **Primary endpoint**: Evaluate the safety, pharmacokinetics and to determine the MTD
- **Secondary endpoint**: Obtain preliminary efficacy data



2. Plan to clinically explore NT-219's efficacy in multiple hard-to-treat oncology indications

Kitov Commercial Drug: Consensi™

Consensi™ is the only NSAID whose labeling indicates reduction of blood pressure and consequent risk reduction of heart attack, stroke and death

Full U.S. Prescribing Information is available at: www.consensi.com

Fixed dose combination of
Celecoxib,
a COX-2 selective NSAID
(the active ingredient in Pfizer's Celebrex®)

+

Amlodipine,
a blood pressure-lowering agent (a calcium channel blocker) *(the active ingredient in Pfizer's Norvasc®)*

Simultaneous treatment of osteoarthritic pain and hypertension

- Approved for marketing by U.S. FDA on May 31, 2018
- Clinical data showed Consensi™ was more effective at lowering blood pressure than amlodipine alone
- Clinical data also demonstrated beneficial renal function measures
- Formulated with 200 mg celecoxib and three different dosages (2.5, 5, 10 mg) of amlodipine
- Manufactured by Dexcel Pharma – Israel's largest private pharmaceutical company

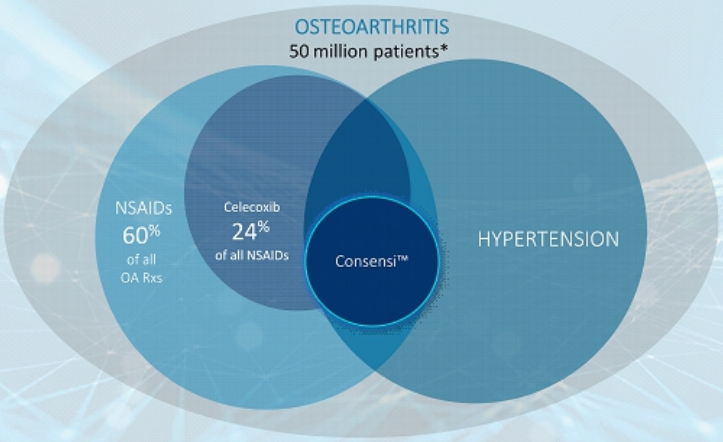
**Celebrex® is a registered trademark of G.D. Searle LLC (a subsidiary of Pfizer Inc.).*
Norvasc® is a registered trademark of Pfizer Inc.

Consensi™ U.S. target markets

Consensi™ targets osteoarthritis (OA) patients currently treated with NSAIDs (celecoxib as well as others) who also suffer from existing or newly diagnosed hypertension

ARTHRITIS PREVALENCE*

- More than 50 million adults in the U.S. have doctor-diagnosed osteoarthritis
- 67 million people are expected to have doctor-diagnosed osteoarthritis by 2030



HYPERTENSION PREVALENCE**

- 29% of U.S. adults older than 18
- 65% of U.S. adults older than 60

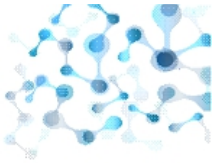
COMORBIDITIES

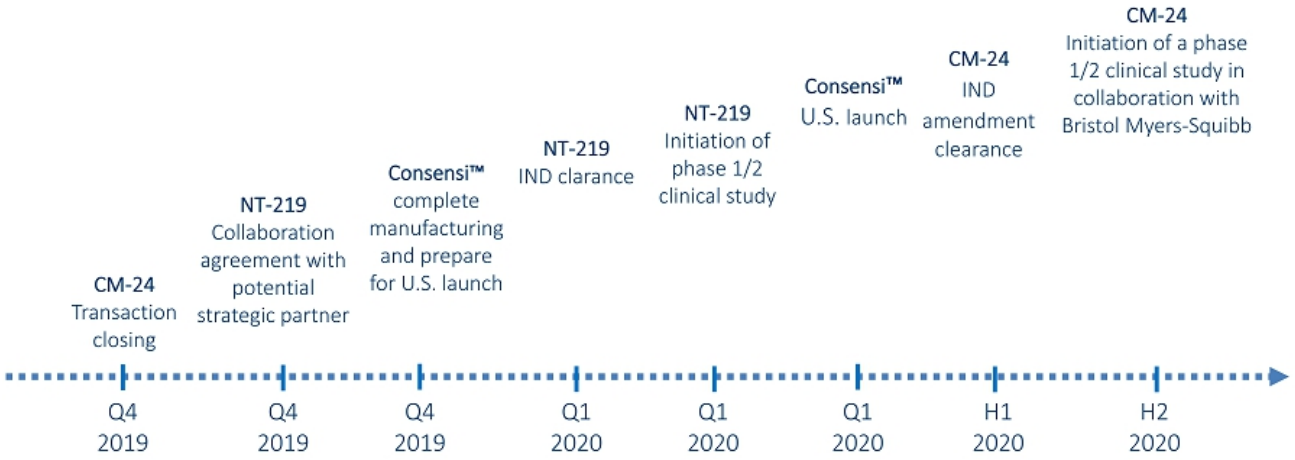
- 44% of adults with high blood pressure have osteoarthritis**

** Arthritis Foundation: http://www.arthritis.org/ ** Hypertension Among Adults in the United States: National Health and Nutrition Examination Survey, 2011–2012*

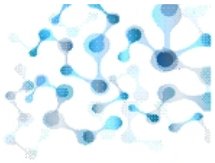
Consensi™ commercialization partners

Milestones




CM-24
Transaction closing
Q4 2019
NT-219
Collaboration agreement with potential strategic partner
Q4 2019
Consensi™
complete manufacturing and prepare for U.S. launch
Q4 2019
NT-219
IND clarance
Q1 2020
NT-219
Initiation of phase 1/2 clinical study
Q1 2020
Consensi™
U.S. launch
Q1 2020
CM-24
IND amendment clearance
H1 2020
CM-24
Initiation of a phase 1/2 clinical study in collaboration with Bristol Myers-Squibb
H2 2020

Attractive opportunity



A clinical-stage company advancing first-in-class oncology therapies

CM-24 – Inhibitor of CEACAM1

NT-219 – Dual inhibitor of IRS 1/2 and STAT3

- ✓ Two clinical stage assets targeting significant unmet needs
- ✓ Strong partners and collaborators
- ✓ Commercial stage drug to provide additional cash flow
- ✓ Institutional healthcare focused investors
- ✓ Cash resources:
  - ✓ $8M cash as of June 19
  - ✓ Additional $3.5M upon CM-24 closing
  - ✓ $7.5M minimum revenues from Consensi™ in next 3 years
- ✓ Current market cap. $22M*

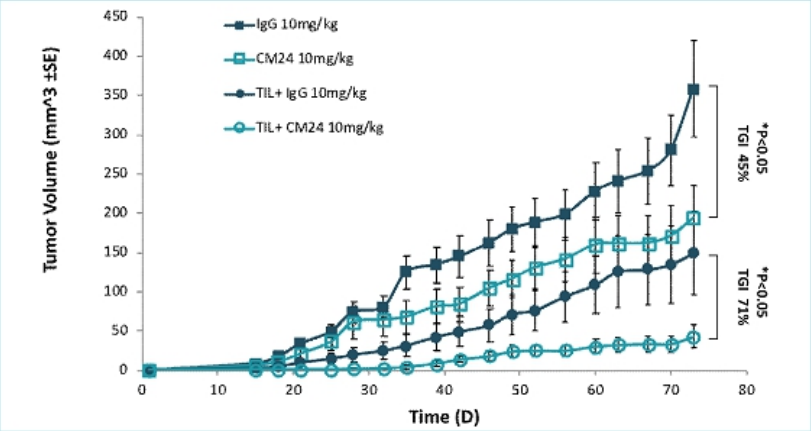
* As of October 15th, 2019, including CM-24 transaction and investment shares


kitov
PHARMA
We are committed to providing cancer patients with
first-in-class therapies to OVERCOME tumor drug resistance,
ENHANCE treatment response and SLOW tumor progression
Contact us:
Email: IR@kitovpharma.com
www.kitovpharma.com

Appendix A - CM24

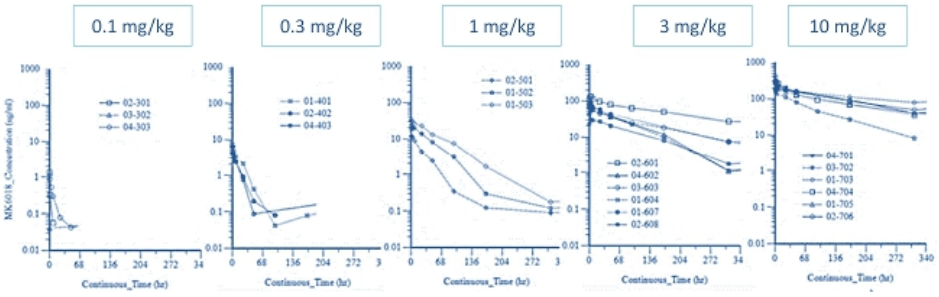
Inhibition of Melanoma Growth Following CM-24 and CM24 + TIL Treatment

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



Phase 1 PK Data

Saturation was not reached with doses up to 10mg/kg



Slower clearance with increasing dose

Higher half-life with increasing dose

Appendix B - NT219

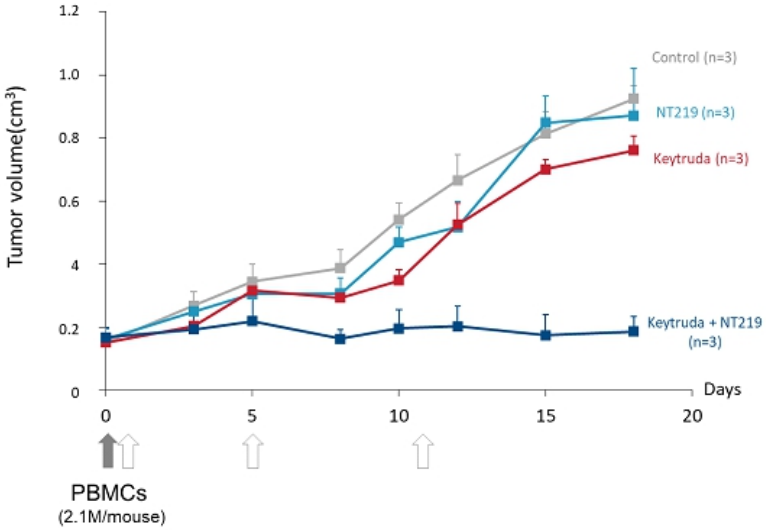
NT219 Re-sensitizes Tumors to Anti-PD1

PDX model

Humanized PDX of Esophagus Cancer

Drug

Pembrolizumab (Keytruda®)



* Double autologous model - Tumors & PBMCs are from the same patient (#RA236) | Keytruda - 6mg/kg IP, NT219 - 60mg/kg IV

NT219 Overcomes Resistance to Gemcitabine in Pancreatic Cancer PDX Models

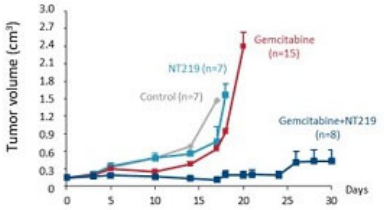
PDX model

Pancreatic Cancer

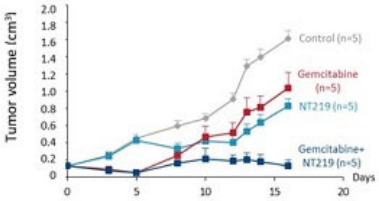
Drug

Gemcitabine (Gemzar®)

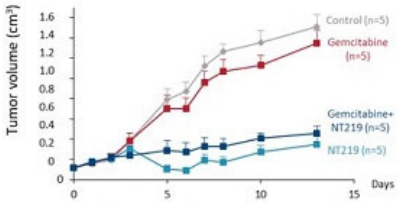
Pancreatic cancer (Patient A) PDX



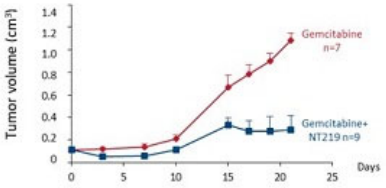
Pancreatic cancer (Patient B) PDX



Pancreatic cancer (Patient C) PDX



Pancreatic cancer (Patient D) PDX



Additional newly released data for NT-219 in reversing Pancreatic Cancer drug resistance is available on AACR PanCan poster:
http://kitovpharma.investorroom.com/index.php?s=151

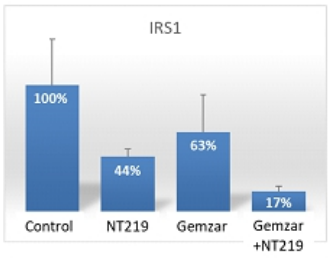
RNAseq Analysis of Tumors Following Treatment Confirming NT-219 Mechanism of Action

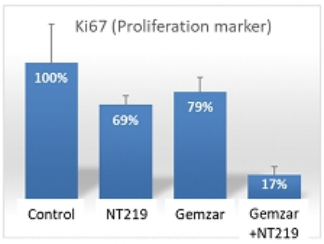
PDX model

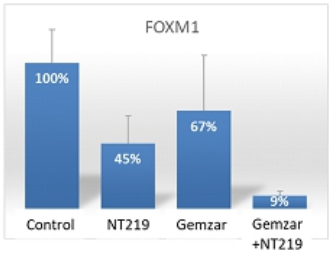
Pancreatic Cancer

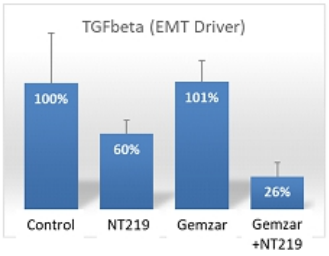
Drug

Gemcitabine (Gemzar®)









Selected Publications

UC San Diego School of Medicine

Michael Karin

ORIGINAL ARTICLE

Targeting colorectal cancer via its microenvironment by inhibiting IGF-1 receptor-insulin receptor substrate and STAT3 signaling

E Sanchez-Lopez[1], E Flashner-Abramson[2], S Shalapour[1], Z Zhong[1], K Tamiguchi[1,3], A Levitzki[2] and M Karin[1]

האוניברסיטה העברית בירושלים
THE HEBREW UNIVERSITY OF JERUSALEM

Alexander Levitzki

SHORT COMMUNICATION

Targeting melanoma with NT157 by blocking Stat3 and IGF1R signaling

E Flashner-Abramson[1], S Klein[1], G Mullin[1], E Shoshan[2], R Song[2], A Shir[1], Y Langut[1], M Bar-Eli[2], H Reuveni[1,4,5,6] and A Levitzki[1,6]

THE UNIVERSITY OF TEXAS MD Anderson Cancer Center

Menashe Bar-Eli

Published OnlineFirst May 7, 2013; DOI: 10.1158/0008-5472.CAN-12-3385

Therapeutics, Targets, and Chemical Biology

Cancer Research

Therapeutic Destruction of Insulin Receptor Substrates for Cancer Treatment

Hadas Reuveni[1,2,3,4], Ehat Flashner-Abramson[2,3], Lilach Steiner[1,2], Kirill Makedonski[1,2], Renduo Song[2], Alexei Shir[1], Meenhard Herlyn[5], Menashe Bar-Eli[2,3], and Alexander Levitzki[1,4]

UBC THE UNIVERSITY OF BRITISH COLUMBIA

Michael Cox

Published OnlineFirst September 29, 2014; DOI: 10.1158/1535-7163.MCT-13-0642

Small Molecule Therapeutics

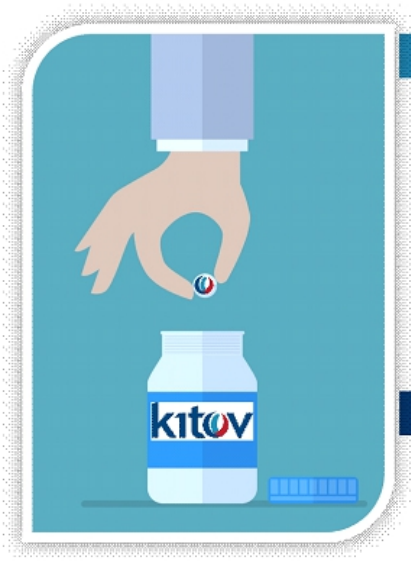
Molecular Cancer Therapeutics

The Tyrphostin NT157 Suppresses Insulin Receptor Substrates and Augments Therapeutic Response of Prostate Cancer

Naokazu Ikuki[1,2], Maryar Ghaffari[1,3], Hadas Reuveni[4,5], Mitali Pandey[1], Leden Fadi[1], Haruhiko Azuma[6], Martin E. Gleave[1,6], Alexander Levitzki[4], and Michael E. Cox[1,6]

Appendix C - Consensi™ Clinical Data

Medical Rationale



Celecoxib (the active ingredient in Pfizer's Celebrex®)

- The only widely prescribed selective COX-2 NSAID approved in the U.S. (unlike non-selective NSAIDs, celecoxib carries limited gastrointestinal risks)
- Since 2005, has an FDA-mandated "black box" label warning of increased cardiovascular risks
- According to FDA, cardiovascular risks can occur as early as the first few weeks of using an NSAID, and may increase with longer use

WARNING: CARDIOVASCULAR AND GASTROINTESTINAL RISKS
See full prescribing information for complete boxed warning

Cardiovascular Risk

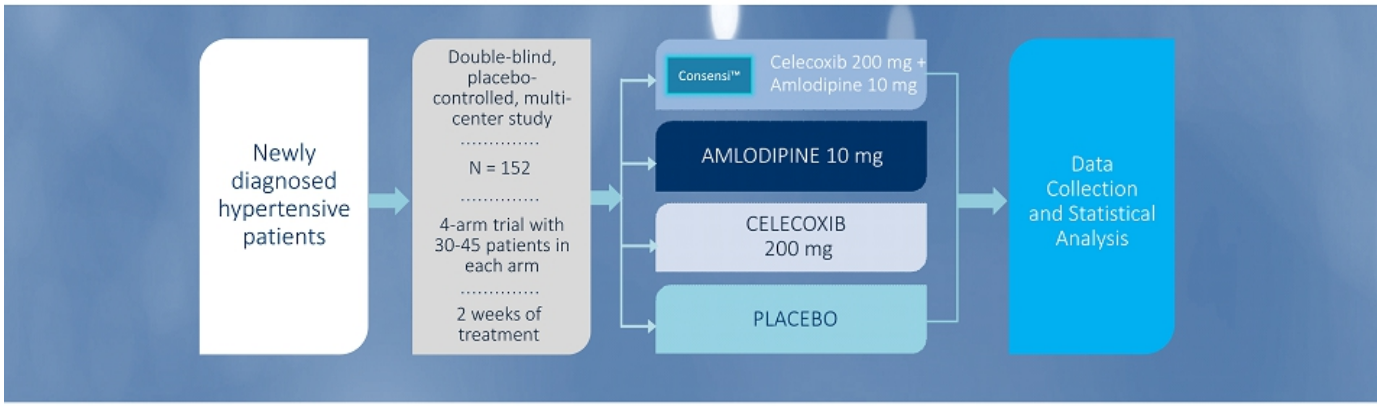
- **CELEBREX, may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal. All NSAIDs may have a similar risk. This risk may increase with duration of use. Patients with cardiovascular disease or risk factors for cardiovascular disease may be at greater risk. *(5.1,14.7)***

Amlodipine (the active ingredient in Pfizer's Norvasc®)

- Calcium channel blocker; anti-hypertensive
- Unlike other blood pressure-lowering drug groups – such as diuretics, ACE inhibitors, and angiotensin II receptor antagonists – calcium channel blockers do not cause deterioration of renal function, including possible acute renal failure*

* The FDA Safety Information and Adverse Event Reporting Program; http://www.fda.gov/Safety/MedWatch/SafetyInformation/ucm270998.htm

Consensi™ Phase III Trial Design

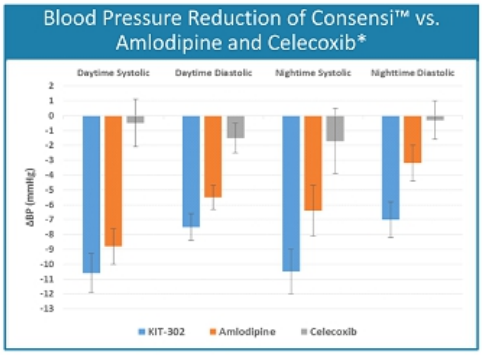


Primary endpoint

Demonstrate that the reduction in blood pressure in the Consensi™ arm is **at least 50% of the reduction in the amlodipine arm**

Measurement of pain was not required by FDA

Consensi™ Phase III Trial Results



Consensi™ demonstrated even better BP reduction than same amount of amlodipine given without celecoxib

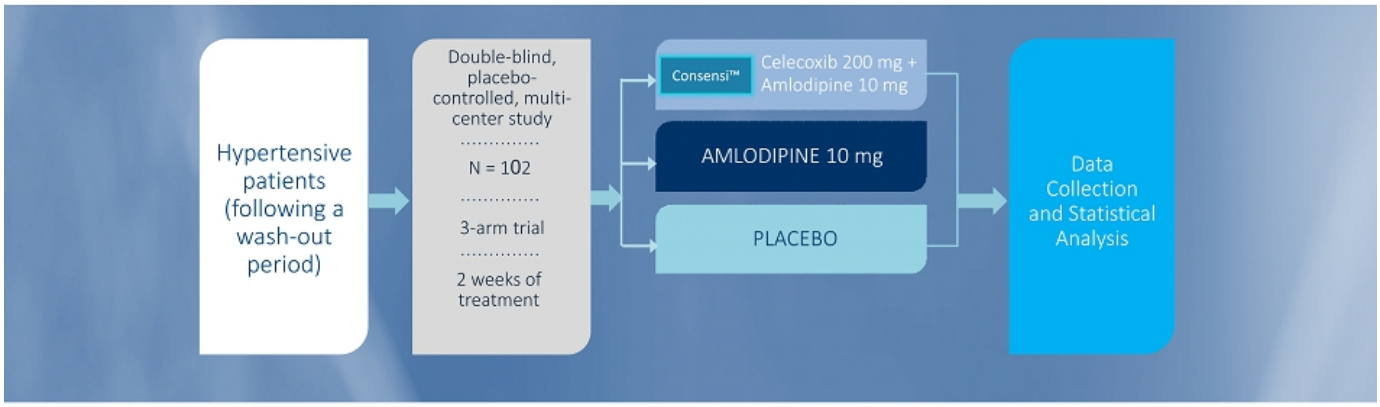
* Error bars – standard error of mean

- Primary efficacy endpoint was successfully achieved (P=0.001)
- Demonstrated 2.5x better blood pressure reduction than FDA requirement (50% of amlodipine arm)
- Demonstrated consistent reduction in all measures of blood pressure
- Observed beneficial renal functions:

Measure	Consensi™	Amlodipine
Creatinine plasma level reduction	-3.22 µmol/L	-2.55 µmol/L
Peripheral edema (% patients)	8.2%	15.6%

- Additional Phase III/IV clinical trial to scientifically validate the renal benefits (not required for NDA submission) was completed. Topline results were announced in October, 2017

Consensi™ Phase III/IV Clinical Trial Design



Primary endpoint

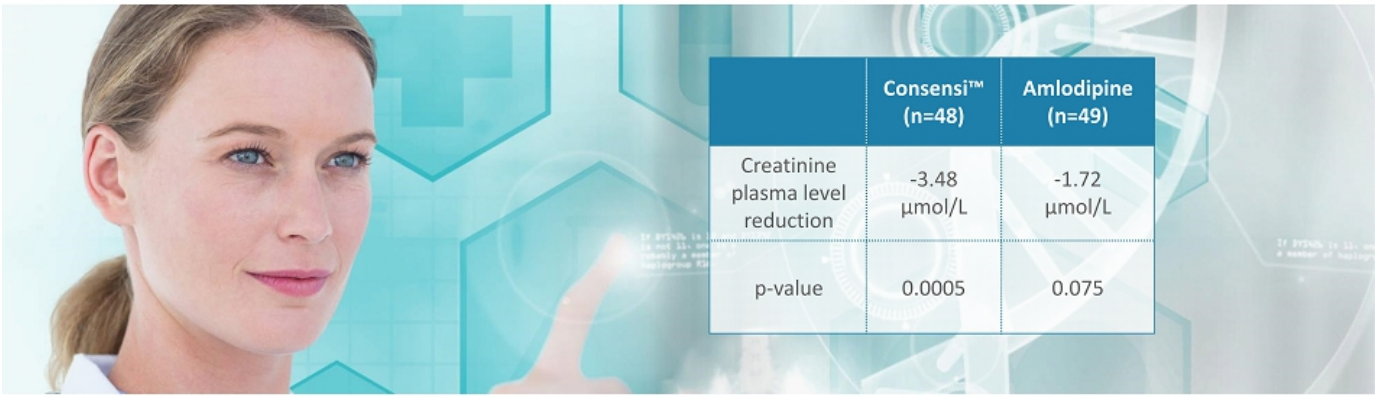
Demonstrate that the reduction in blood pressure in the Consensi™ arm is **at least 50% of the reduction in the amlodipine arm**

Secondary endpoints

Improvements of renal function measurements

Consensi™ Phase III/IV Clinical Trial Results

- Primary efficacy endpoint successfully met (p=0.019), thus Phase III trial results validated
- Statistically significant reduction of serum creatinine observed vs. baseline
- Consensi™ enhanced the creatinine reduction by an average of 102% vs. amlodipine alone
- Consensi™ demonstrated systolic blood-pressure reduction comparable to amlodipine



	Consensi™ (n=48)	Amlodipine (n=49)
Creatinine plasma level reduction	-3.48 µmol/L	-1.72 µmol/L
p-value	0.0005	0.075