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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 November 2017

Commission File Number: 001-37643

**KITOV PHARMACEUTICALS HOLDINGS 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): \_\_\_\_

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Kitov Pharmaceuticals Holdings Ltd. (the “Company” or the “Registrant”) is announcing that on November 29, 2017 it 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 in the Investor Relations section of the Registrant’s website at [www.kitovpharma.com](http://www.kitovpharma.com).

Attached hereto are the following exhibits:

Exhibit 99.1 [Company Presentation – November 2017](#)

## 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 PHARMACEUTICALS HOLDINGS LTD.**

November 29, 2017

By: /s/ Simcha Rock  
Simcha Rock  
Chief Financial Officer



Innovative Biopharmaceuticals

# CORPORATE PRESENTATION

November 2017



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



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; 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 Annual Report on Form 20-F for the year ended December 31, 2016 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>.

# Company Profile

Innovative Biopharmaceutical Company

Leveraging Deep Regulatory and Drug Development Expertise



## DIVERSE PIPELINE ADDRESSING LARGE MARKETS

- Lead drug candidate KIT-302 developed to treat osteoarthritic pain and hypertension
- KIT-302 NDA filed with FDA; assigned PDUFA date: May 31, 2018
- NT-219 – small molecule designed to overcome cancer drug resistance

## PROVEN TEAM

- KIT-302 manufacturing and CMC work partnered with Dexcel Pharma, Israel's largest private pharmaceutical company
- Management team with proven track record in drug development, NDA submissions and FDA approvals

## COMPELLING VALUE

- Founded in 2010; publicly traded on TASE 2013; IPO on NASDAQ in November 2015
- Tickers: KTOV (ADSs); KTOVW (Warrants)
- Cash on hand (as of October 31, 2017): \$8.6M; no debt
- Market Cap: \$27M\*
- Issued & outstanding capital equivalent to 11.2 million ADSs\*\*

\* As of November 27, 2017  
\*\* Each ADS = 20 ordinary shares

# Experienced Management



**Paul Waymack, M.D., Sc.D.**  
Chairman of the Board & Chief Medical Officer  
Former FDA medical officer



**Isaac Israel**  
Chief Executive Officer  
Former CEO of BeeContact (TASE: BCNT),  
NextGen Biomed (TASE: NXGN)



**Simcha Rock, CPA, MBA**  
Chief Financial Officer  
Former Senior VP Edmond de Rothschild



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



**Hadas Reuveni, Ph.D.**  
Founder & Chief Technology Officer - TyrNovo  
Formerly at Keryx (NASDAQ: KERX)



**EDMOND  
DE ROTHSCHILD**

**TEVA**



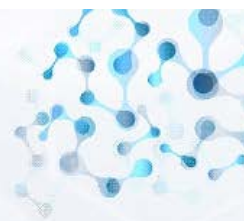
**KERYX**  
BIOPHARMACEUTICALS, INC.

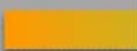

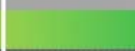
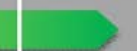



**Dexcel<sup>®</sup>**  
pharma



# Pipeline



Drug	Therapeutic Field	Preclinical	Phase I/II	Phase III	Submission	Approval
KIT-302	Osteoarthritis pain and hypertension					PDUFA target date: May 31, 2018
NT-219	Oncology					



# About KIT-302

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 blood pressure elevation



- KIT-302's pivotal Phase III trial successfully met its primary efficacy endpoint - announced in December 2015. Data showed that KIT-302 is more effective at lowering blood pressure than amlodipine alone
- Formulated with 200 mg celecoxib and three different dosages (2.5, 5, 10 mg) of amlodipine
- Regulatory submission path with U.S. FDA is under a Special Protocol Assessment (SPA) and 505(b)2 route
- KIT-302 NDA was submitted to and filed by FDA. PDUFA date expected on May 31, 2018

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

**kitov**

# Medical Rationale



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

- The only widely prescribed selective COX-2 NSAID approved in the US (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

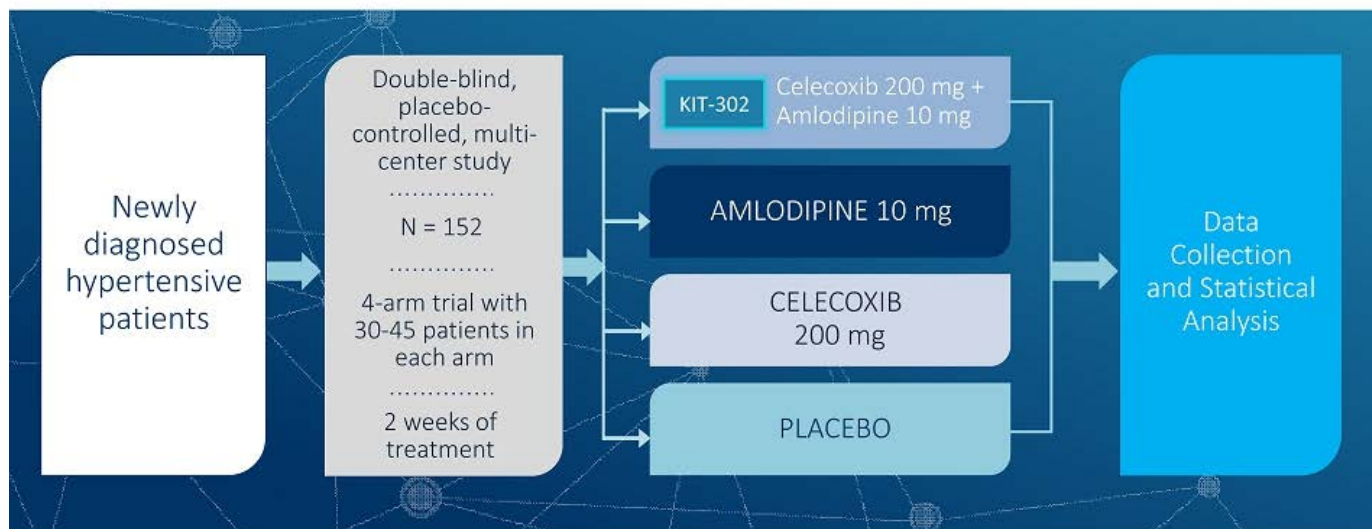
**WARNING: CARDIOVASCULAR AND GASTROINTESTINAL RISKS**  
*See full prescribing information for complete boxed warning*  
**Cardiovascular Risk**  
• CELEBREX, may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal. All NSAIDs may 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\*

# KIT-302 Phase III Trial Design

(under Special Protocol Assessment from FDA)

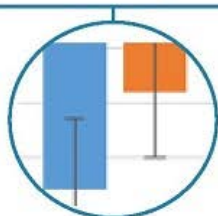
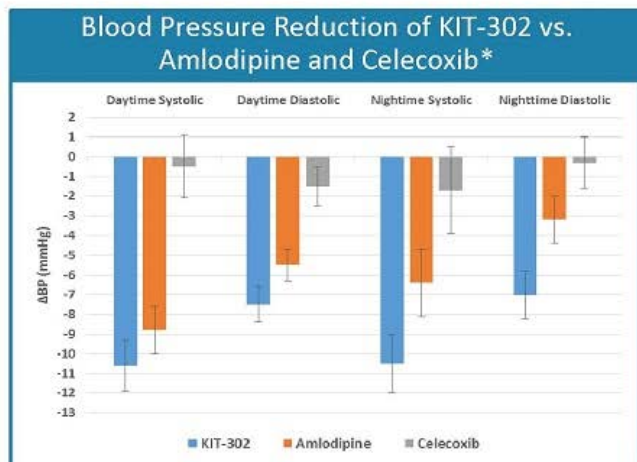


## Primary endpoint

Demonstrate that the reduction in blood pressure in the KIT-302 arm is **at least 50% of the reduction in the amlodipine arm**

Measurement of pain was not required by FDA

# KIT-302 Phase III Trial Results



KIT-302 demonstrated even better BP reduction than same amount of amlodipine given without celecoxib

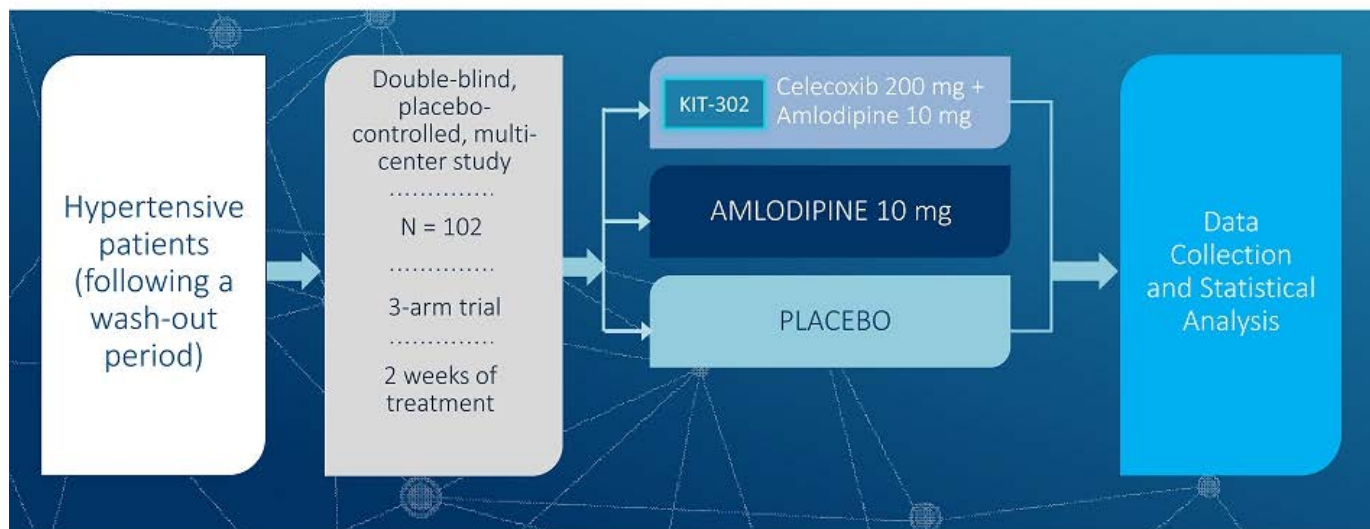
\* Error bars – standard error of mean

- 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	KIT-302	Amlodipine
Creatinine plasma level reduction	-3.22 $\mu\text{mol/L}$	-2.55 $\mu\text{mol/L}$
Peripheral edema (% patients)	8.2%	15.6%

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

# KIT-302 Second Phase III/IV Trial Design



## Primary endpoint

Demonstrate that the reduction in blood pressure in the KIT-302 arm is **at least 50% of the reduction in the amlodipine arm**

## Secondary endpoints

Improvements of renal function measurements



# KIT-302 Second Phase III/IV Trial Results



- Primary efficacy endpoint successfully met ( $p=0.019$ ), thus first Phase III trial results validated
- Statistically significant reduction of serum creatinine observed vs. baseline
- KIT-302 enhanced the creatinine reduction by an average of 102% vs. amlodipine alone
- KIT-302 demonstrated systolic blood-pressure reduction comparable to amlodipine
- Completion and submission of the report to FDA expected by January 2018

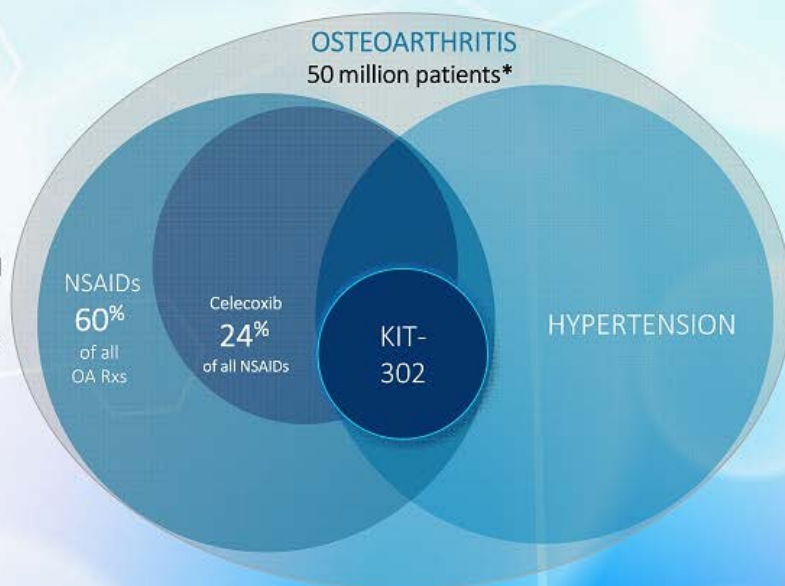


# KIT-302 US Target Markets

KIT-302 targets osteoarthritic 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 US have doctor-diagnosed osteoarthritis
- 67 million people are expected to have doctor-diagnosed osteoarthritis by 2030



## HYPERTENSION PREVALENCE\*\*

- 29% of US adults older than 18
- 65% of US 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



# KIT-302 Benefits All Stakeholders

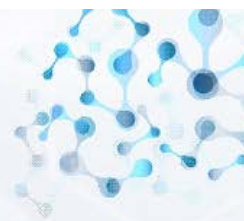
KIT-302 is expected to be the only NSAID whose labeling will indicate reduction of blood pressure and consequent risk reduction of heart attack, stroke and death





# KIT-302 Commercialization



# Pipeline



Drug	Therapeutic Field	Preclinical	Phase I/II	Phase III	Submission	Approval
KIT-302	Osteoarthritis pain and hypertension					PDUFA target date: May 31, 2018
NT-219	Oncology					

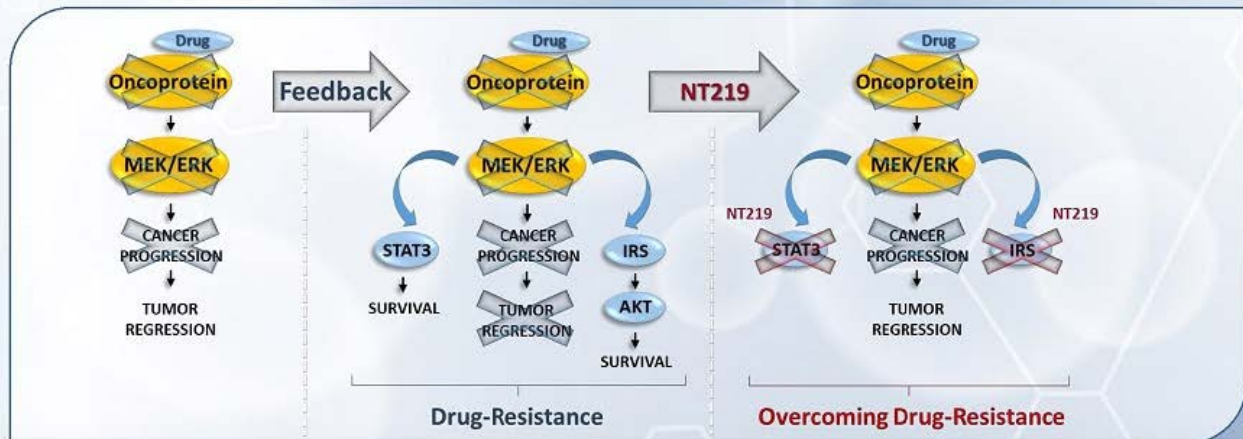
# NT-219: Overcoming Cancer Drug Resistance

- Recently acquired majority (92%\*) shares in privately held TyrNovo Ltd.
- TyrNovo develops NT-219, a first-in-class small molecule that prevents, reverses, and delays resistance to anti-cancer drugs
  - Dual inhibitor of STAT3 and IRS1/2: two signal pathways associated with drug resistance
  - Demonstrated outstanding efficacy in patient-derived xenograft (PDX) models
- Favorable response received from FDA in a pre-IND meeting
- Preclinical work ongoing; IND expected in 12-18 months
- Initial clinical trial expected in pancreatic cancer patients in combination with gemcitabine (Gemzar®)
- Long-term strategy to develop NT-219, in combination with other oncology drugs for additional indications, in collaboration with strategic partners who have expressed solid preliminary interest in the drug

\*including 27% contracted, pending closing

# NT-219: Mechanism of Action

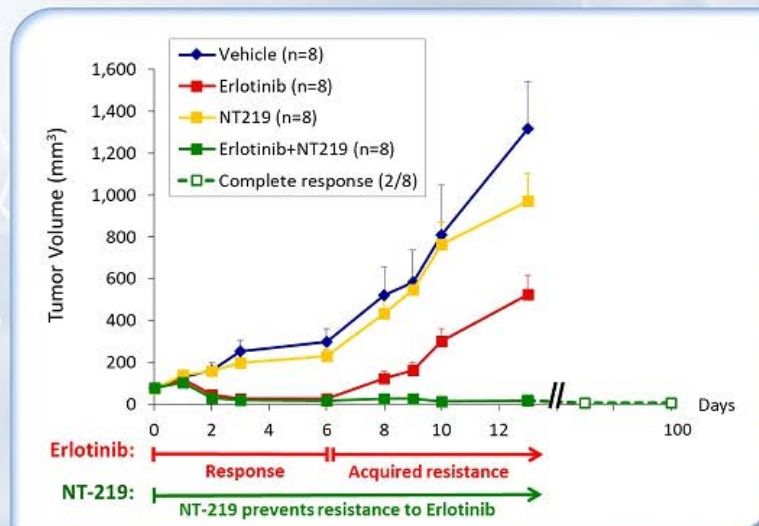
- Anti-cancer drugs induce activation of two feedback pathways, STAT3 and IRS, leading to drug resistance
- NT-219 simultaneously targets STAT3 and IRS1/2, thereby overcoming drug resistance and extending the positive response to the drugs
- Inhibition of STAT3 may also activate anti-cancer immunity





# Results in PDX Models

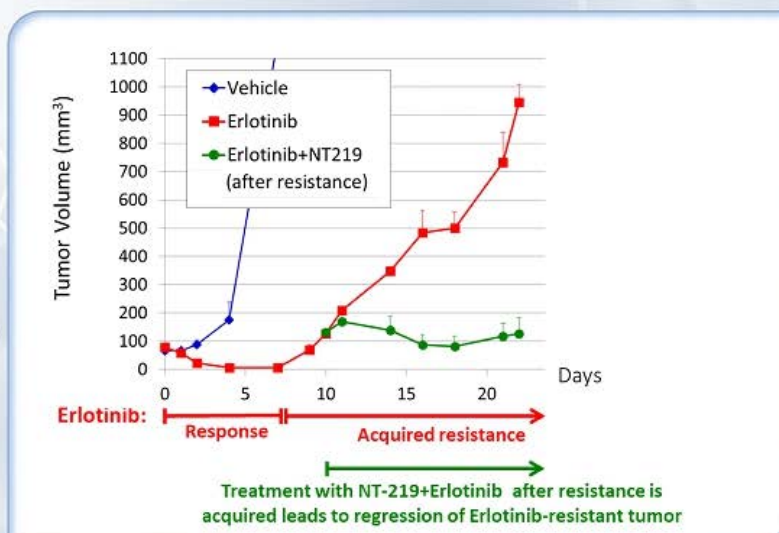
NT-219 Prevents Acquired Resistance to EGFR Inhibitor (Tarceva®) in Head and Neck Cancer



When administered in combination with Tarceva®, no resistance was developed

# Results in PDX Models (cont'd)

NT-219 Reverses Existing Resistance to Tarceva® in Head and Neck Tumors

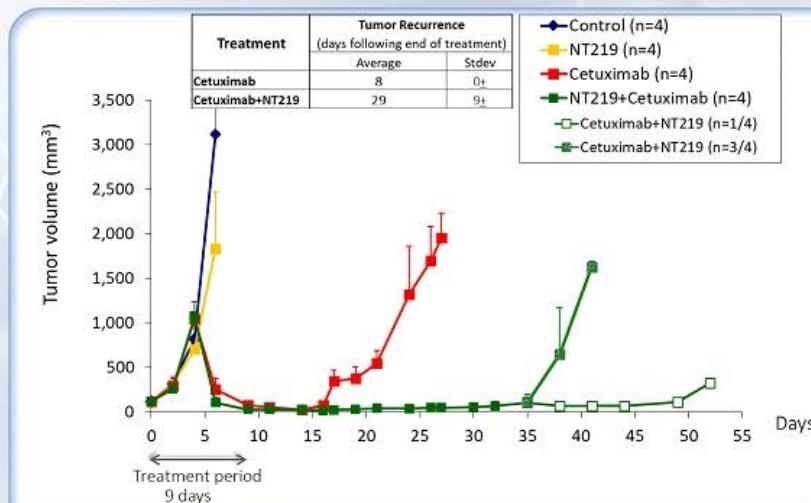


When administered after development of resistance, NT-219 reversed resistant tumors to sensitive



# Results in PDX Models (cont'd)

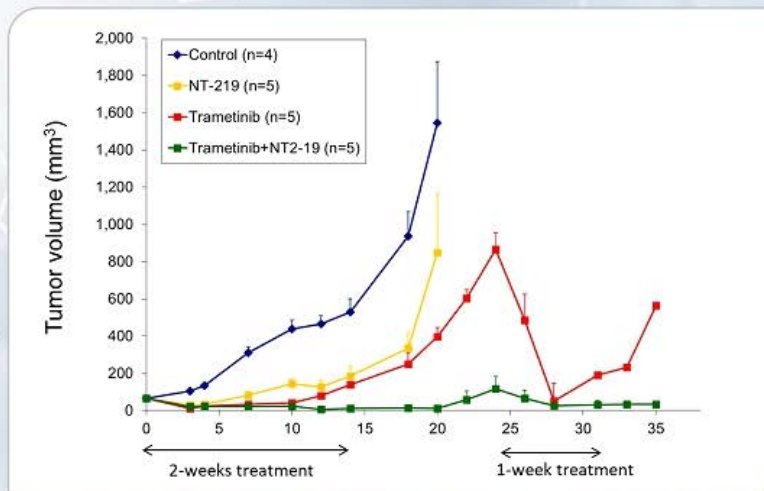
## NT-219 Delays Recurrence of Tumors of Head and Neck with Cetuximab



Tumors treated with NT-219 and Cetuximab took much longer to develop following treatment discontinuation

# Results in PDX Models (cont'd)

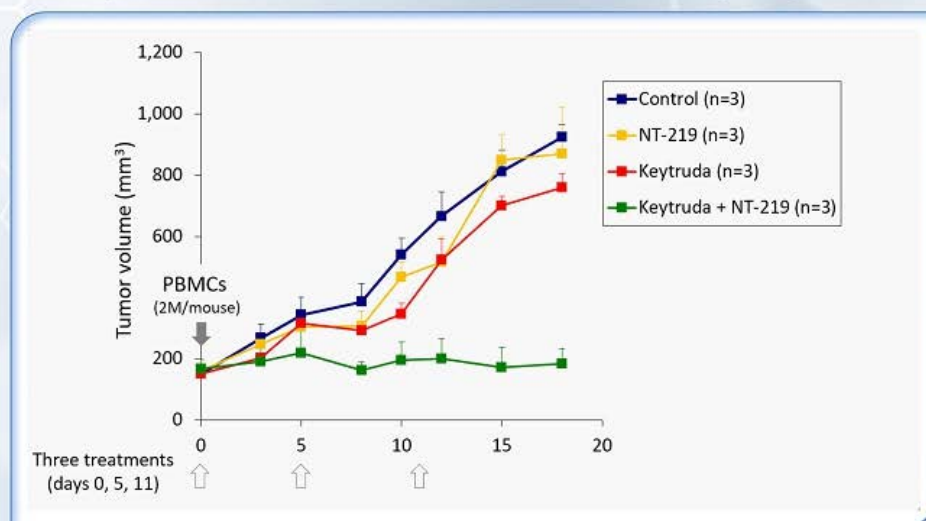
## NT-219 Prevents Acquired Resistance to MEK Inhibitor (Mekinist®) in Mutated-BRAF Anaplastic Thyroid Cancer



When administered in combination with Mekinist® (Trametinib), a prolonged effect was observed

# Results in Immuno-Oncology PDX Model in Combination with Keytruda®

NT-219 Converts Non-Responding Tumors to Keytruda® to Responders in Humanized PDX of Esophagus Cancer



Double autologous model - tumors and PBMCs of the same patient

# Summary of Demonstrated Efficacy

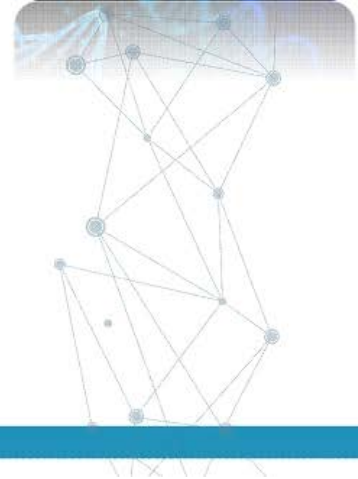
NT-219 will be developed in combination with approved oncology drugs to increase efficacy, expand target population, and extend treatment duration



	TYPE	DRUG (TRADE NAME)	CANCER TYPE	COMPANY
Targeted Drugs	Antibody	Cetuximab (Erbix <sup>®</sup> )	Head and Neck	Merck / Eli Lilly
		Cetuximab (Erbix <sup>®</sup> ) + FOLFOX/FOLFIRI	Colon (wt KRAS)	
	Kinase Inhibitors	Erlotinib (Tarceva <sup>®</sup> )	Head and Neck	Roche / Astellas
		Afatinib (Giotrif <sup>®</sup> )	Head and Neck	Boehringer Ingelheim
		Osimertinib (Tagrisso <sup>®</sup> )	Lung	AstraZeneca
		Vemurafenib (Zelboraf <sup>®</sup> )	Melanoma	Roche
		Trametinib (Mekinist <sup>®</sup> )	Thyroid	Novartis
		Everolimus (Afinitor <sup>®</sup> )	Uterine Adenosarcoma	Novartis
Chemotherapy		Gemcitabine (Gemzar <sup>®</sup> )	Pancreatic	Eli Lilly
		5FU, Oxaliplatin (FOLFOX)	Colon	Sanofi, Sun, Teva
		Docetaxel (Taxotere <sup>®</sup> )	Prostate	Sanofi
Immunotherapy	Antibody	Pembrolizumab (Keytruda <sup>®</sup> )	Melanoma, NSCLC, Head and Neck	Merck and Co.

# Selection of First Indication

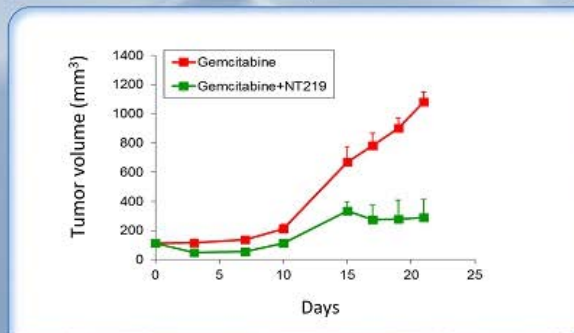
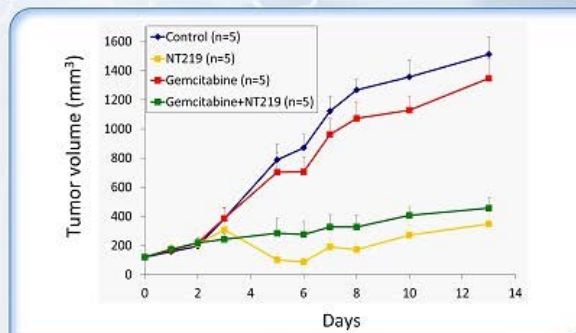
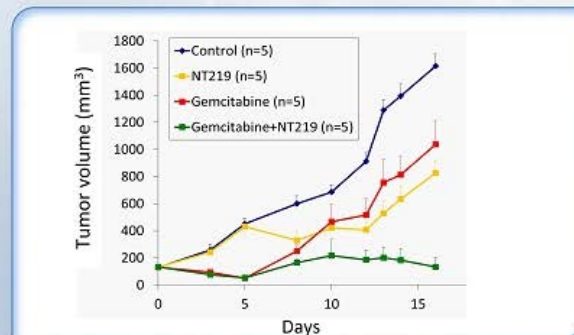
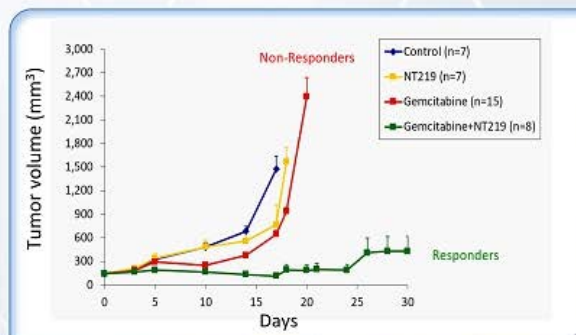
- Genomic analysis of resistant tumors in the H&N model revealed amplification in KRAS and NF-1 loss
- Since KRAS mutation is associated with 95% of pancreatic tumors, biopsies from four different pancreatic cancer patients were tested
- Results demonstrated beneficial effect of NT-219 in 4/4 biopsies
- Based on these outstanding results, pancreatic cancer was selected as the first indication
- A Phase I/II trial beginning in 2019 will test NT-219 in combination with gemcitabine





# Expected Phase I/II Clinical Trial

NT-219 Converts Non-Responding Tumors to Responders to Gemcitabine in 4/4 PDX Models of Pancreatic Cancer



# Summary



<b>Proven management team</b>	<ul style="list-style-type: none"><li>• Management team with track record in drug development and regulatory expertise</li></ul>
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<b>Balanced and diverse pipeline</b>	<ul style="list-style-type: none"><li>• Lead drug candidate KIT-302 assigned PDUFA date: May 31, 2018</li><li>• NT-219 IND submission expected in 12-18 months</li></ul>
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<b>Large market potential</b>	<ul style="list-style-type: none"><li>• KIT-302 addresses large target population</li><li>• NT-219 has blockbuster potential in multiple malignancies</li></ul>
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<b>Strong IP portfolio</b>	<ul style="list-style-type: none"><li>• KIT-302 is US patent protected through 2030</li><li>• NT-219 composition patent was granted, combination patents are pending</li></ul>
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Innovative Biopharmaceuticals

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