



Corporate Presentation

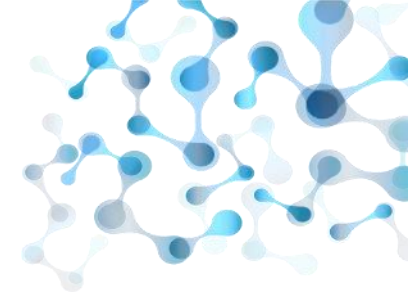
May 2020



Forward-Looking Statements and Safe Harbor

Certain statements in this presentation 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, the intended use of proceeds and 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, 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>.

Kitov Pharma (NASDAQ/TASE:KTOV)



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 novel assets targeting significant unmet needs
- Strong partners and collaborators
- Consensi™: Commercial stage drug to support pipeline development
 - > \$28M-36M of revenues expected in 2020-2022
- Institutional healthcare focused investors
- Financials:
 - ✓ Market cap. ~\$24M*
 - ✓ \$19M cash as of January 1st, 2020 (pro forma**)
 - ✓ 2.8M shares 3-month avg. trading volume

* As of April 30th, 2020

** including net \$3.5M + \$5.5M + \$5.8M raised in January 20, March 20 and April 20 financing transactions respectively

From Development to Commercialization



Program	Indication	Preclinical	Phase 1	Phase 2	Phase 3	Partners	Value Drivers
CM-24	NSCLC and Pancreatic Cancer (combination with nivolumab)					Study initiation Q4:20 Phase 1 data H1:21	
NT-219	R/M solid tumors and Head and Neck (monotherapy and in combination with Erbitux®)					Study initiation Q2:20 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	U.S.: Coeptis Pharmaceuticals China: CSBio S. Korea: Kuhnle Pharmaceutical	U.S. Launch: Q2:20

Multiple data read-outs expected within 15 months

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

Chief Medical Officer

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

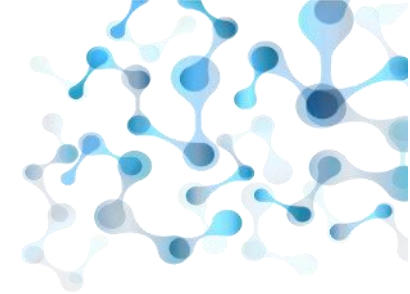
Formerly CFO at Kamada (NASDAQ:KMDA)



Michael Schickler, Ph.D

Head of Clinical Operations

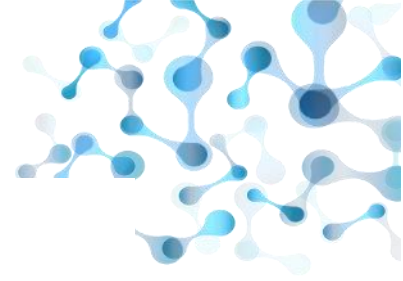
Formerly at Hoffmann-La Roche, CEO at CureTech,



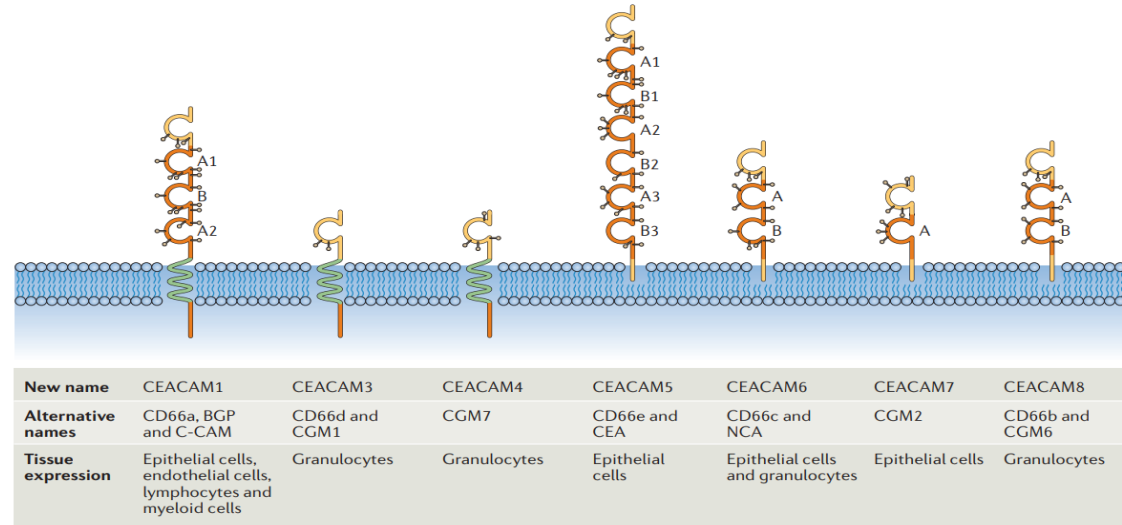
Advancing first-in-class Oncology Therapies

CM-24 – Inhibitor of CEACAM1

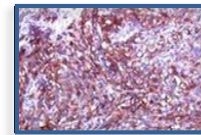
CEACAM1 Plays a pivotal role in the immune system



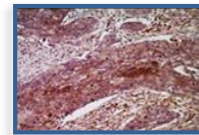
- CEACAM1 (Carcinoembryonic Antigen Cell Adhesion Molecule 1) - member of the Human CEA Family
- Interacts with both CEACAM1 and CEACAM5
- Regulates TIM-3-mediated tolerance and exhaustion*
- High expression in tumor and in tumor-infiltrating immune cells



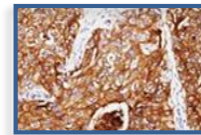
Melanoma (70%)



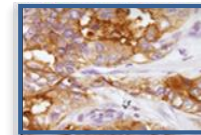
Bladder (96%)



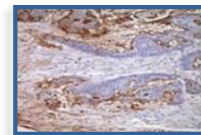
Lung (50%)



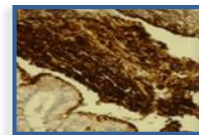
Gastric (74%)



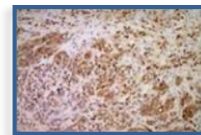
Colon (92%)



Pancreas (94%)

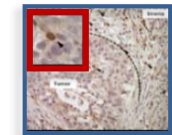


Prostate (63%)

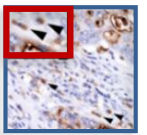


%CEACAM1 staining in tumor

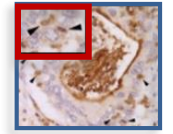
Bladder carcinoma



Colon



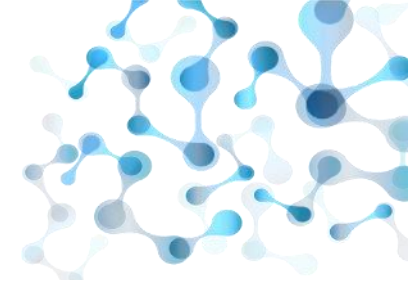
Pancreas



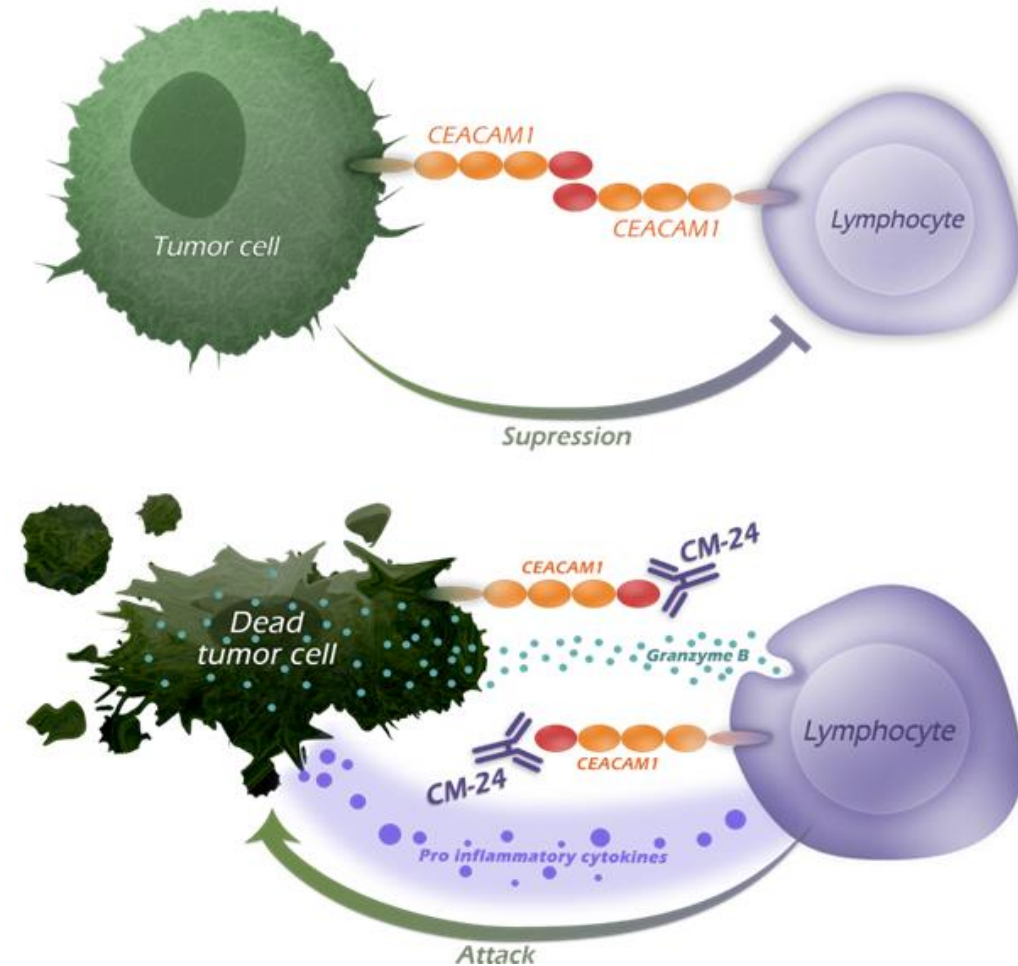
CEACAM1 + Immune cells

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

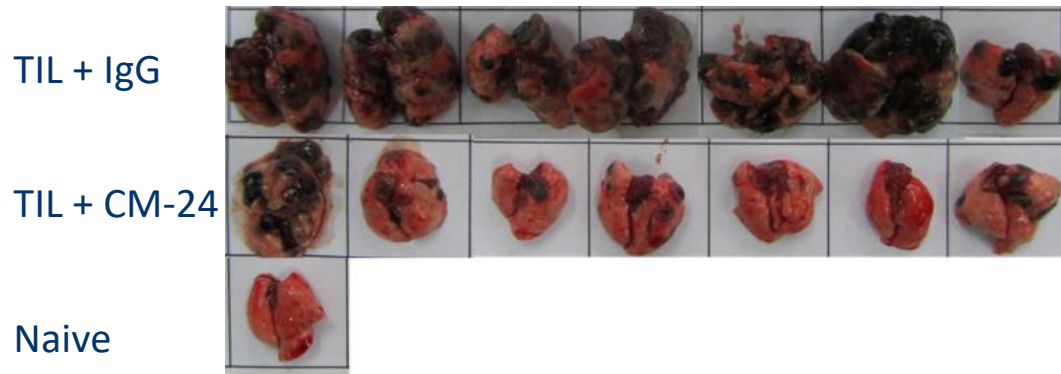
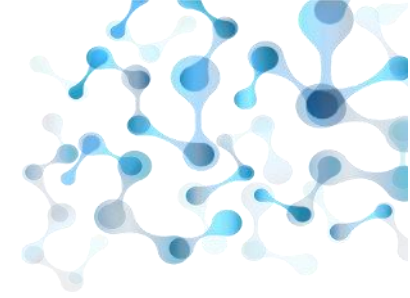
CM-24 MOA: Blocks CEACAM1-mediated interactions



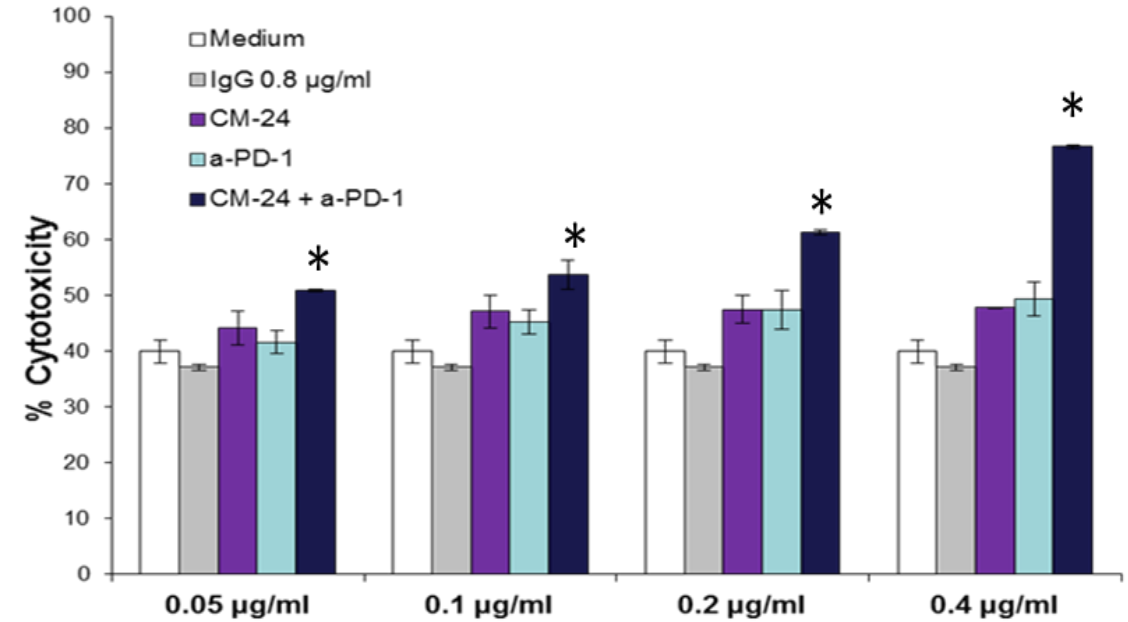
- CM-24 is a humanized IgG4 mAb highly specific to the extracellular domain of CEACAM1 with Nano-molar affinity
- CM-24 prevents CEACAM1-CEACAM1 or CEACAM1-CEACAM5 interaction, thus enhancing the cytotoxic activity of the lymphocytes
- CM-24 activity is manifested in the blockade of:
 - Immune inhibitory signals
 - Angiogenesis
 - Tumor-stroma interaction



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

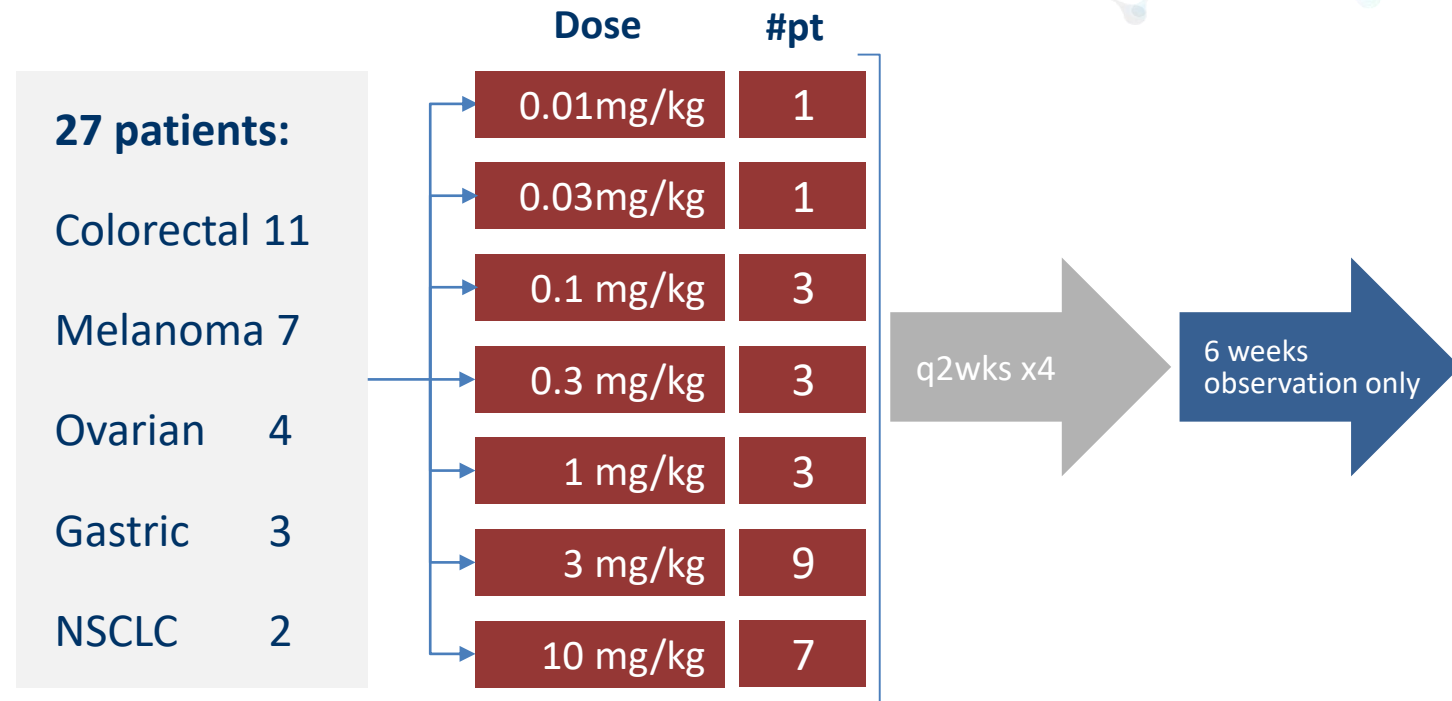
$$CI = \frac{(D)_1}{(D_x)_1} + \frac{(D)_2}{(D_x)_2} < 1 \rightarrow \text{synergism}$$

Significant benefits as both single agent and in combination with α -PD-1

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

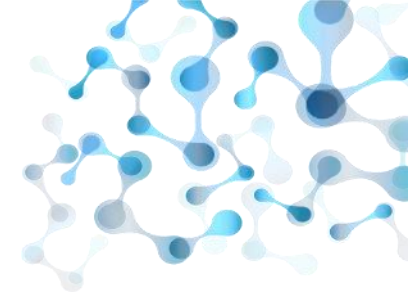


- ✓ No DLTs up to 10 mg/kg
- ✓ No discontinuation of study drug due to an AE
- ✓ No drug related mortalities
- ✓ 29.6% SD (RECIST)

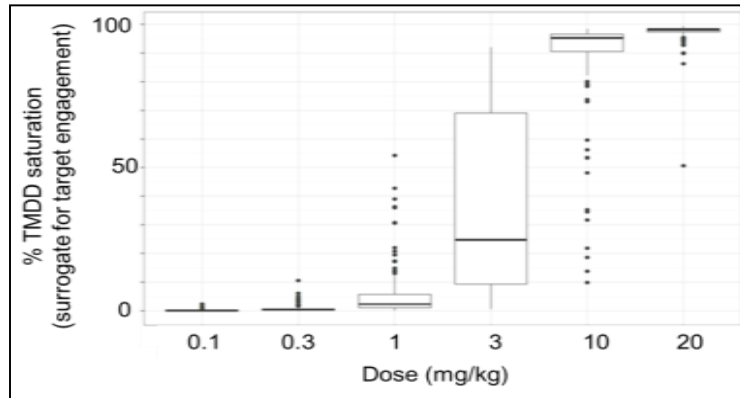
Overall, treatment with CM-24 was well tolerated

PK/PD Modeling Suggests Saturation Kinetics

Higher Doses and Shorter Schedule Required

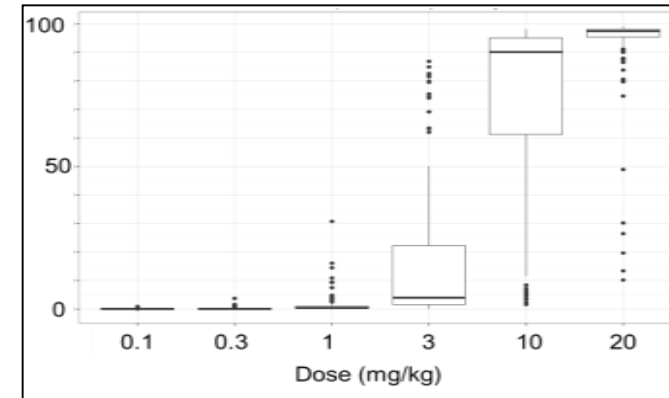


Simulated TMDD saturation at Ctrough with Q2W regimen



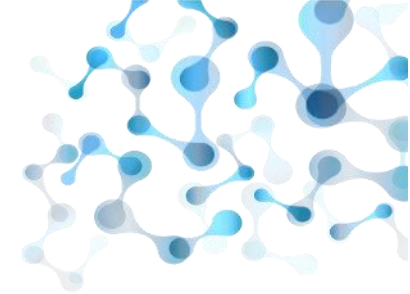
- Consistent with observed PK showing high clearance at doses <10 mg/kg, plot shows low TMDD saturation at low doses
- 10 mg/kg approaches > 90% saturation but >10 mg/kg dose is needed for saturation across population

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

OPDIVO® is administered Q2W or Q4W, and thus represents a better clinical and commercial fit for CM-24 than KEYTRUDA®



Market opportunity: Non-Small Cell Lung Cancer

Rationale for combining Opdivo® + CM-24

- CEACAM1 expression correlates with poor prognosis in NSCLC*
- Preclinical data supports significant synergism
- 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 first 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%****

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

* Dango et al, Lung Cancer 2008; 60:426

**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.

CM-24 Phase 1/2 Study Design



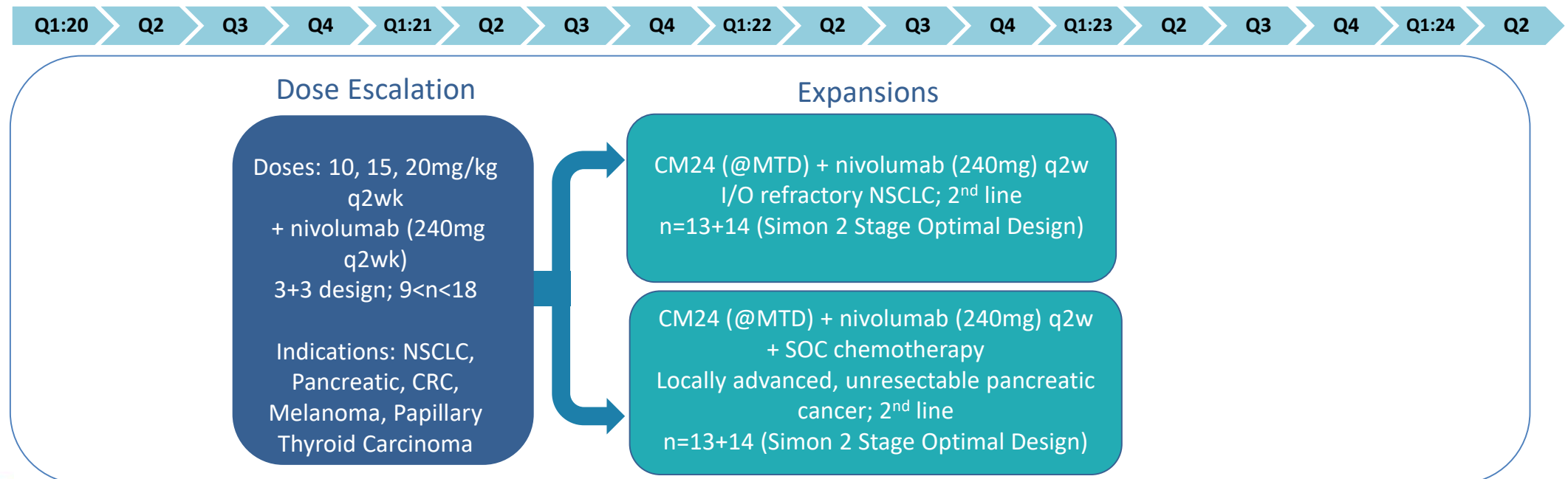
- A Phase 1/2 open label multi center study of CM-24 in combination with nivolumab (Opdivo®) in selected cancer indications (Phase 1), NSCLC and Pancreatic cancer (Phase 2)
- Clinical collaboration with Bristol-Myers Squibb
- Measurement of CEACAM1 based bio-marker

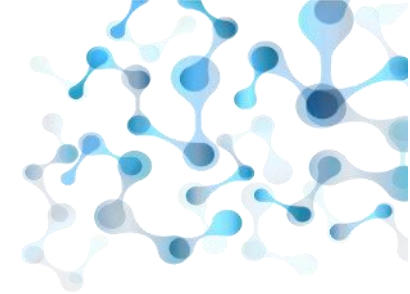
Primary endpoints:

Phase 1: Evaluate the safety, PK and the MTD/RP2 dose

Phase 2: Evaluate preliminary efficacy in 2nd line NSCLC and Pancreatic cancer

- 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

IRS1/2 and STAT3 Role in Cancer Drug Resistance



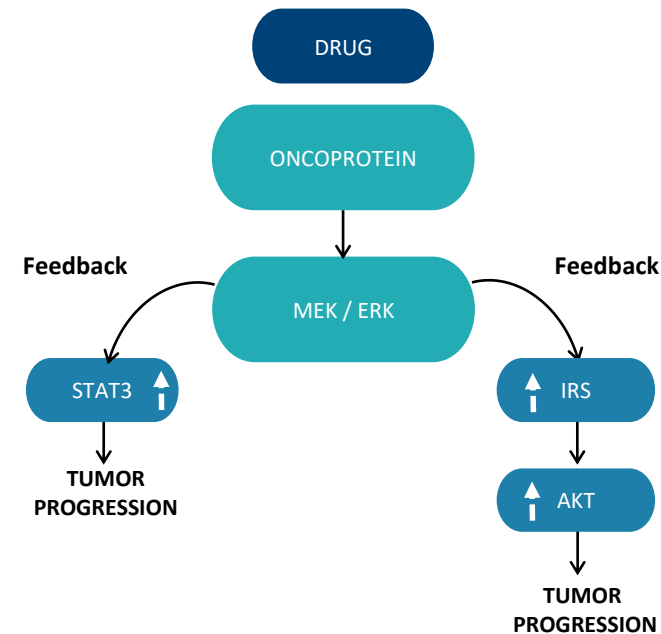
IRS1/2

- 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

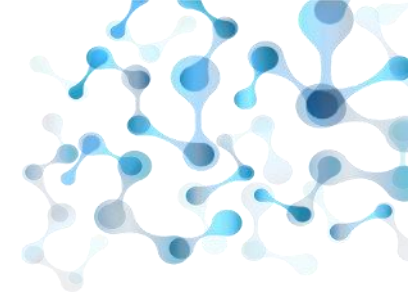
- Active in the JAK/STAT3 immune evasion mechanism of the tumor
- Provides a crucial axis to support cell proliferation and survival

Drug resistance

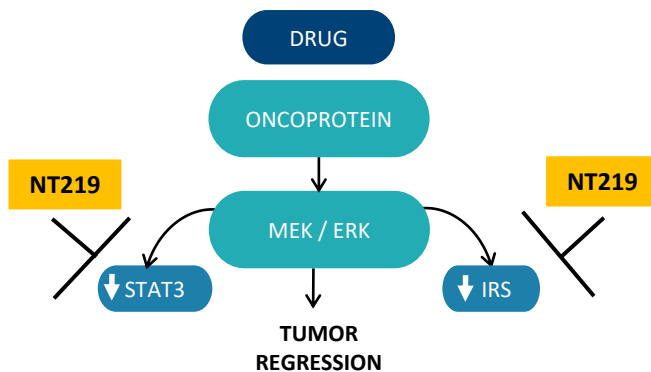


IRS1/2 and STAT3 are key signal transducers activated as a feedback response to anti-cancer drugs, leading to drug resistance

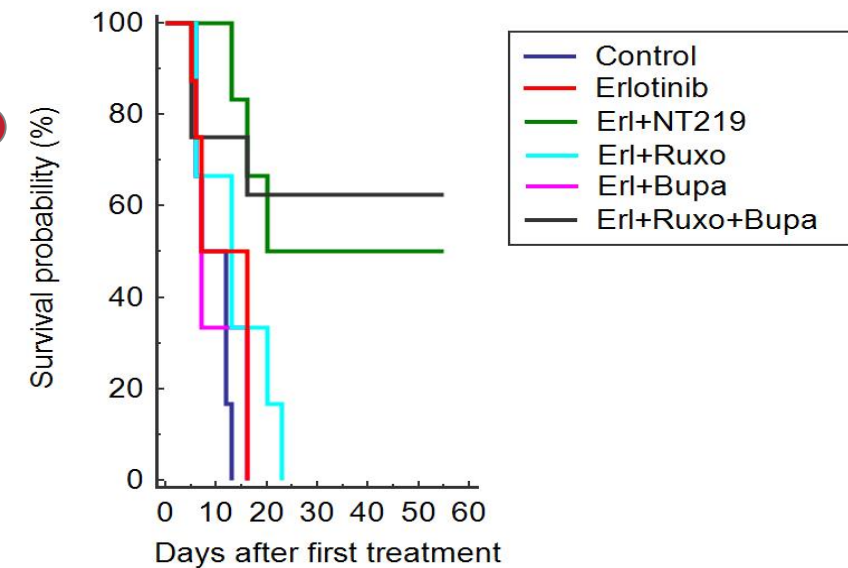
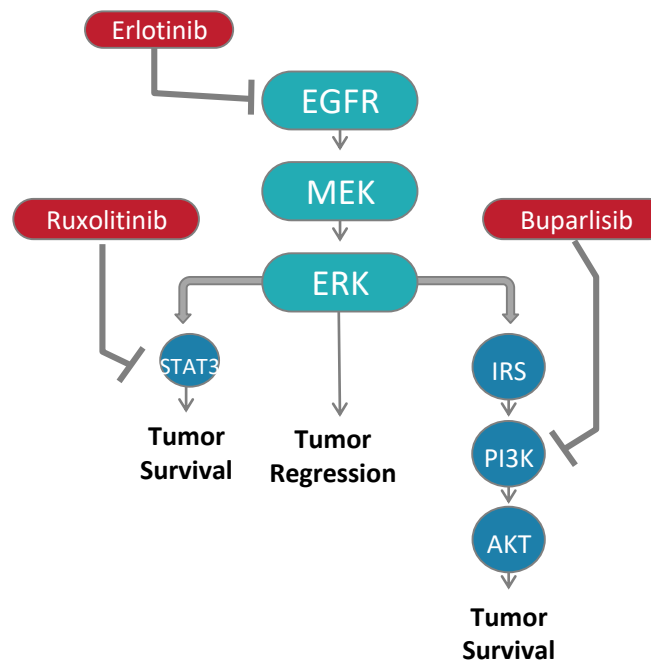
NT-219 MOA: Inhibition of Both STAT3 and IRS is Required to Overcome Resistance



Overcoming drug resistance



PDX of H&N cancer: modeling overcoming drug resistance



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

NT219 Prevents Acquired Resistance to Erlotinib



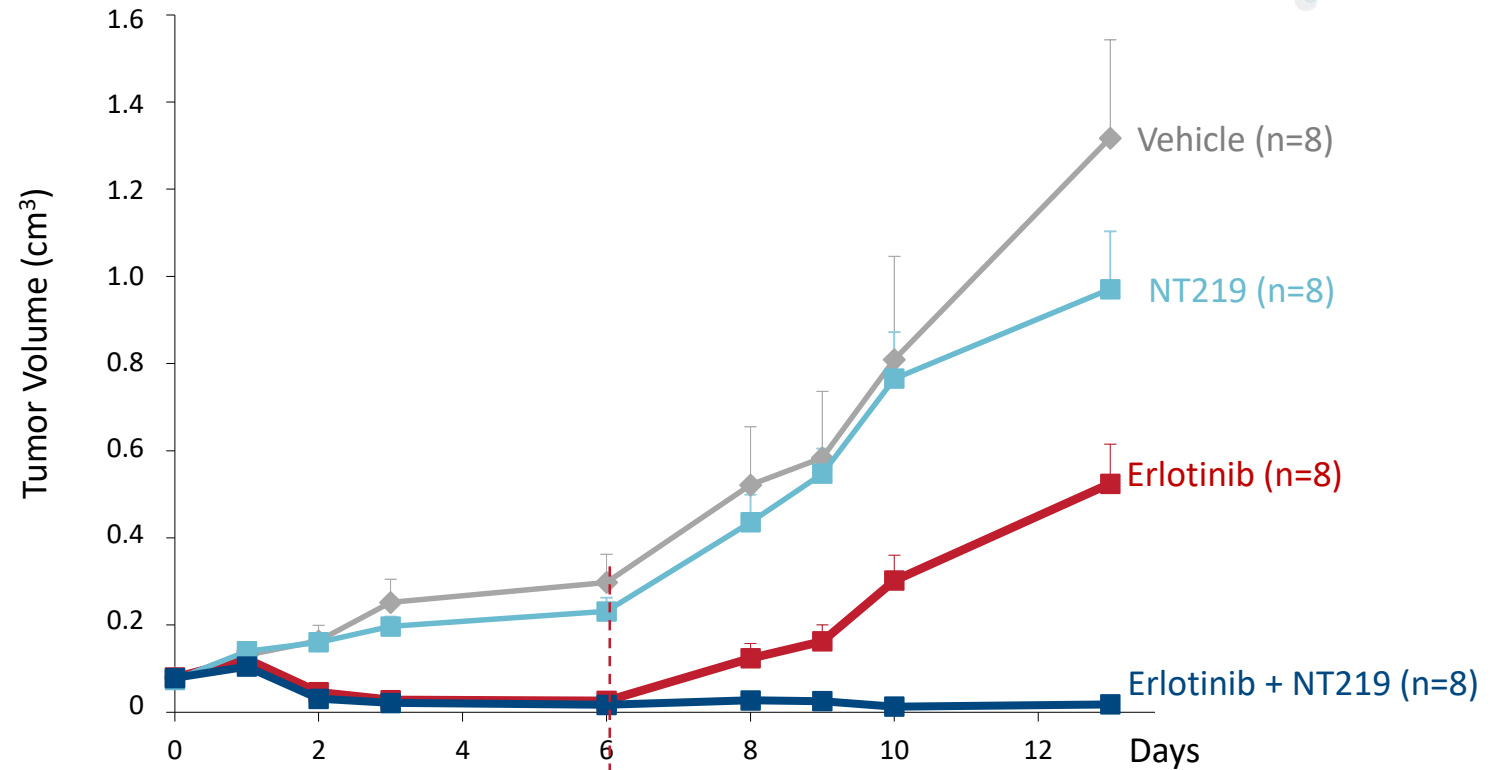
PDX model

Head & Neck Cancer



Drugs

Erlotinib (Tarceva®)



Erlotinib

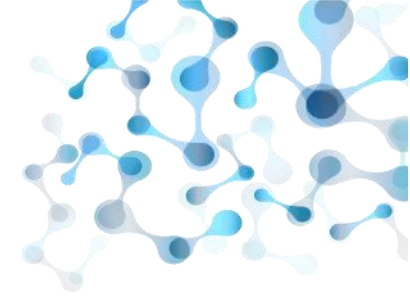
Response

Acquired resistance

NT219 + Erlotinib

NT219 prevents resistance to Erlotinib

NT219 Reverses Erlotinib-acquired Resistance



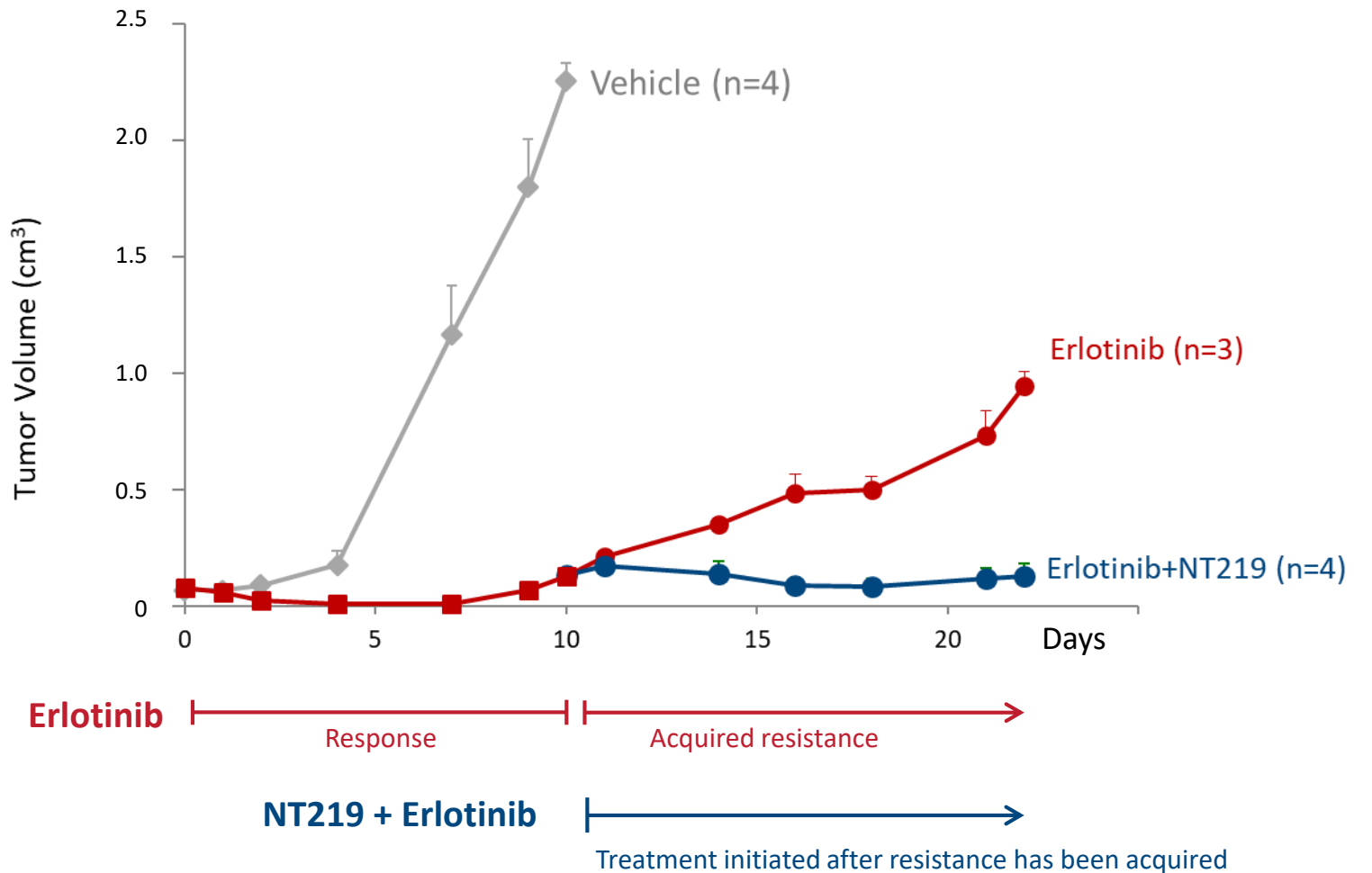
PDX model

Head & Neck Cancer



Drugs

Erlotinib (Tarceva®)



NT219 Delays Tumor Recurrence



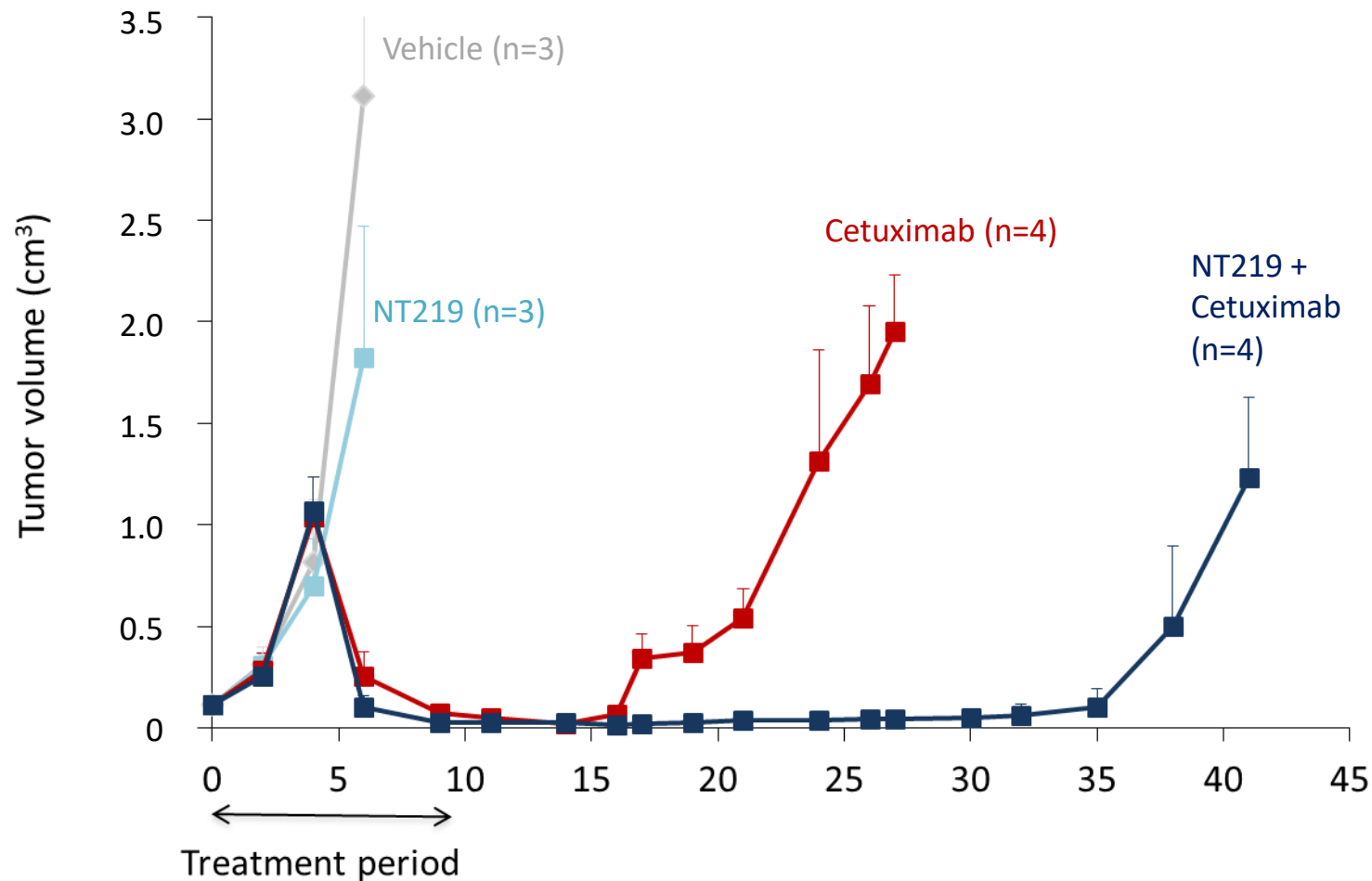
PDX model

Head & Neck Cancer

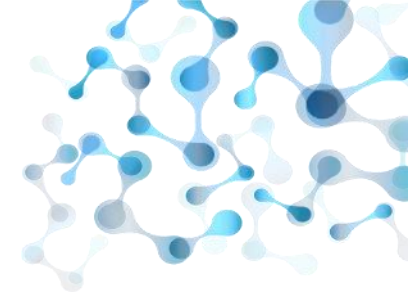


Drug

Cetuximab (Erbix[®])



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

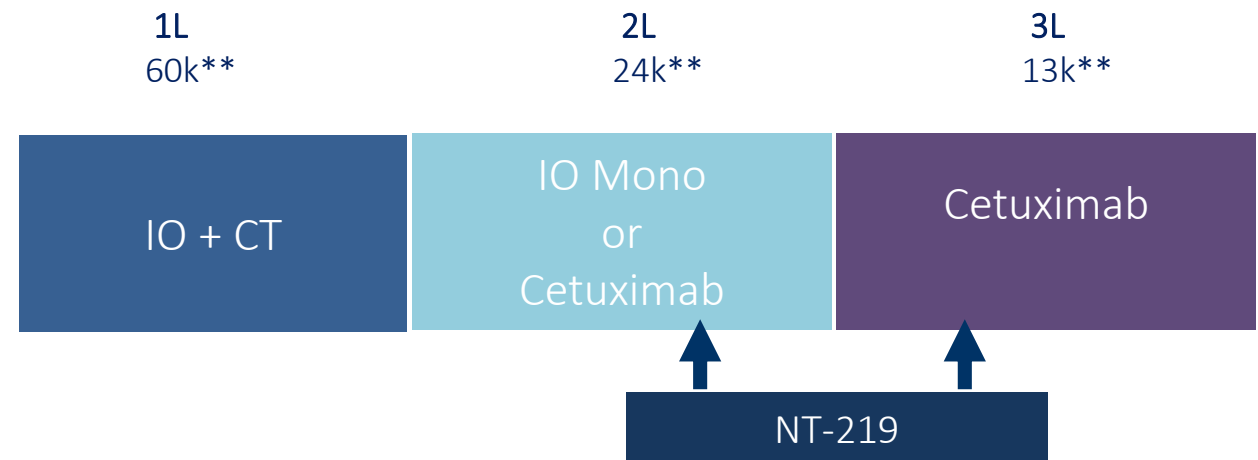


Rationale for combining Cetuximab + NT-219

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

Targeting the unmet medical need

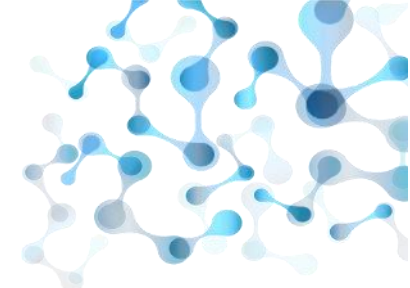
- 1L Standard of care is shifting from chemotherapy towards immuno-oncology + chemotherapy*
- Only < 20% of R/M SCCHN patients respond to anti-PD1s
- Number of new cases/year is expected to be 174,000 by 2024



* 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

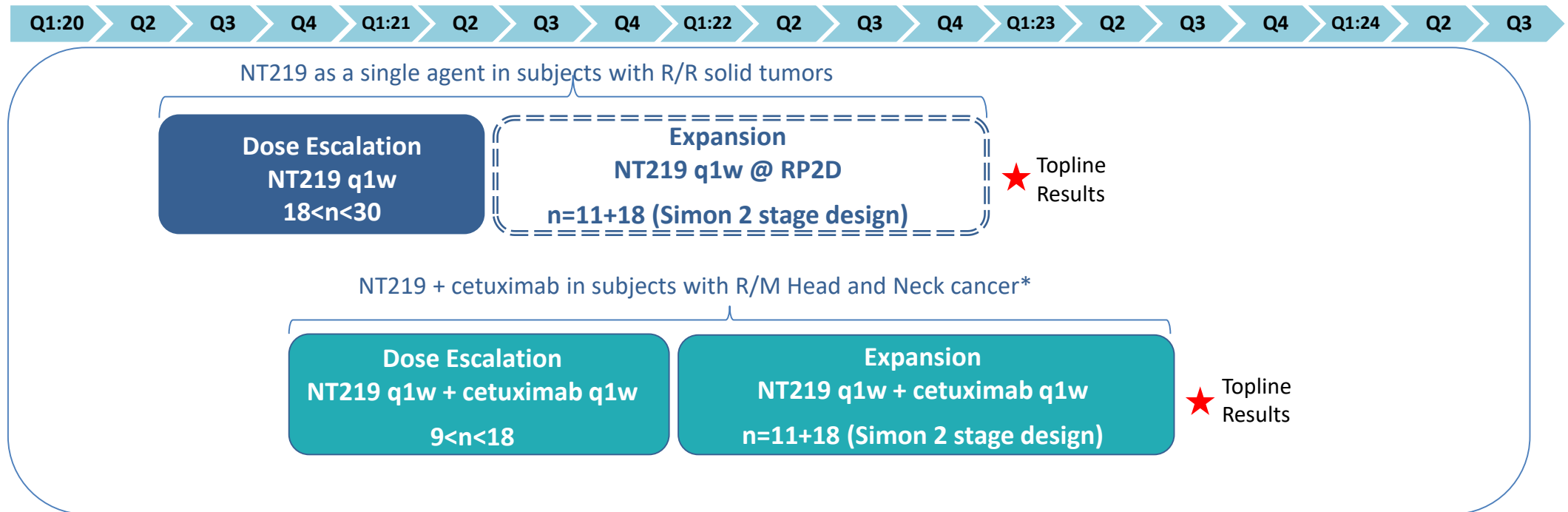
NT-219 + cetuximab has the potential to become an attractive 2-3L therapy



NT-219 Phase 1/2 Study Design

Title: A phase 1/2 study with open-label, dose escalation phase followed by single-arm expansion to assess the safety, tolerability, PK, PD and efficacy of NT219, alone and in combination with Erbitux® (cetuximab) in adults with recurrent or metastatic solid tumors and Head and Neck cancer

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



* Colorectal Adenocarcinoma pts will be recruited in the Dose Escalation phase

⎓ = Indication TBD (expansion not part of the study protocol)



Kitov Commercial Drug: Consensi™

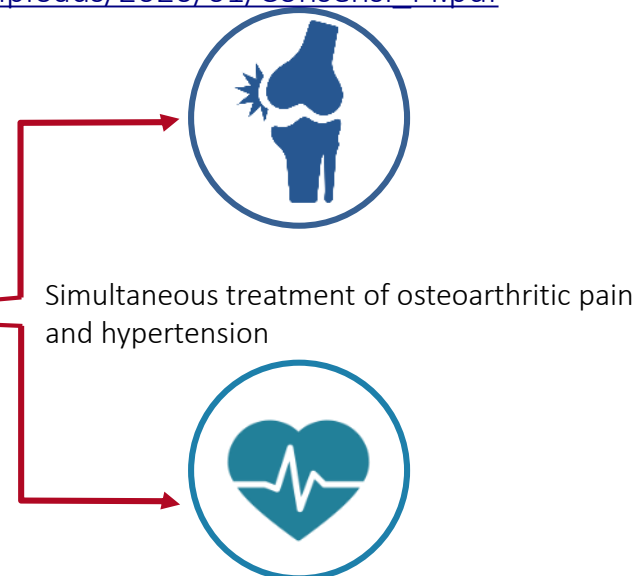
Consensi™ is the only NSAID whose labeling indicates reduction of blood pressure and consequent risk reduction of heart attack, stroke and death

Full U.S. Prescribing Information is available at: : http://coeptispharma.com/wp-content/uploads/2020/01/Consensi_PI.pdf

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®)

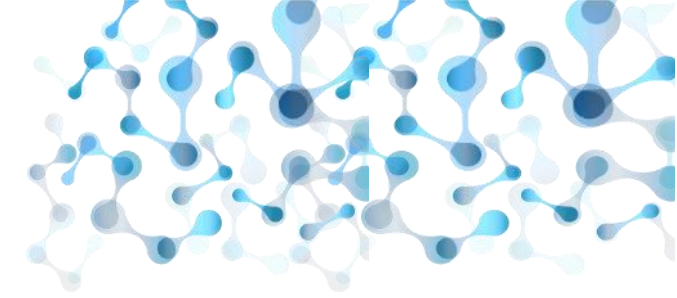


- Approved for marketing by U.S. FDA on May 31, 2018
- Clinical data showed Consensi™ was more effective at lowering blood pressure than amlodipine alone
- Clinical data also demonstrated beneficial renal function measures
- Formulated with 200 mg celecoxib and three different dosages (2.5, 5, 10 mg)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

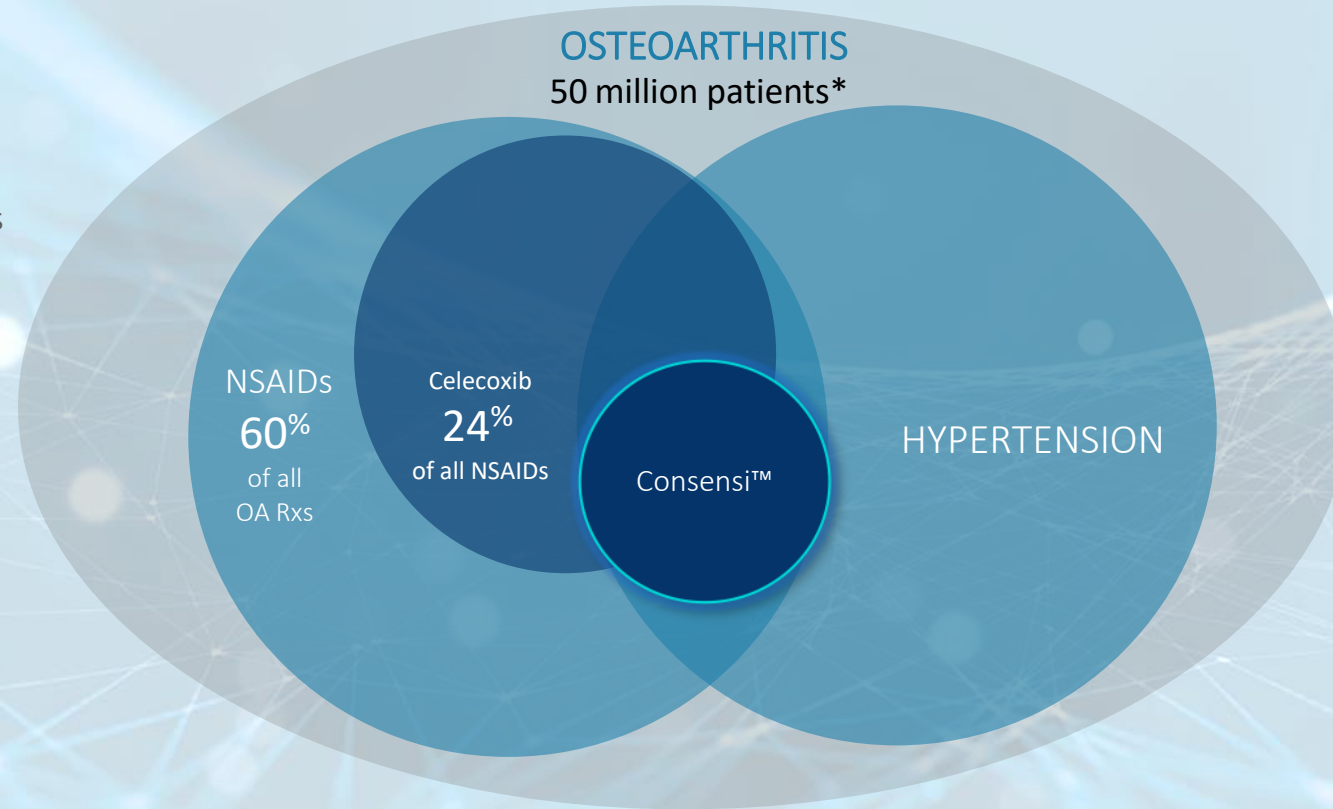
Consensi™ U.S. target markets

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**

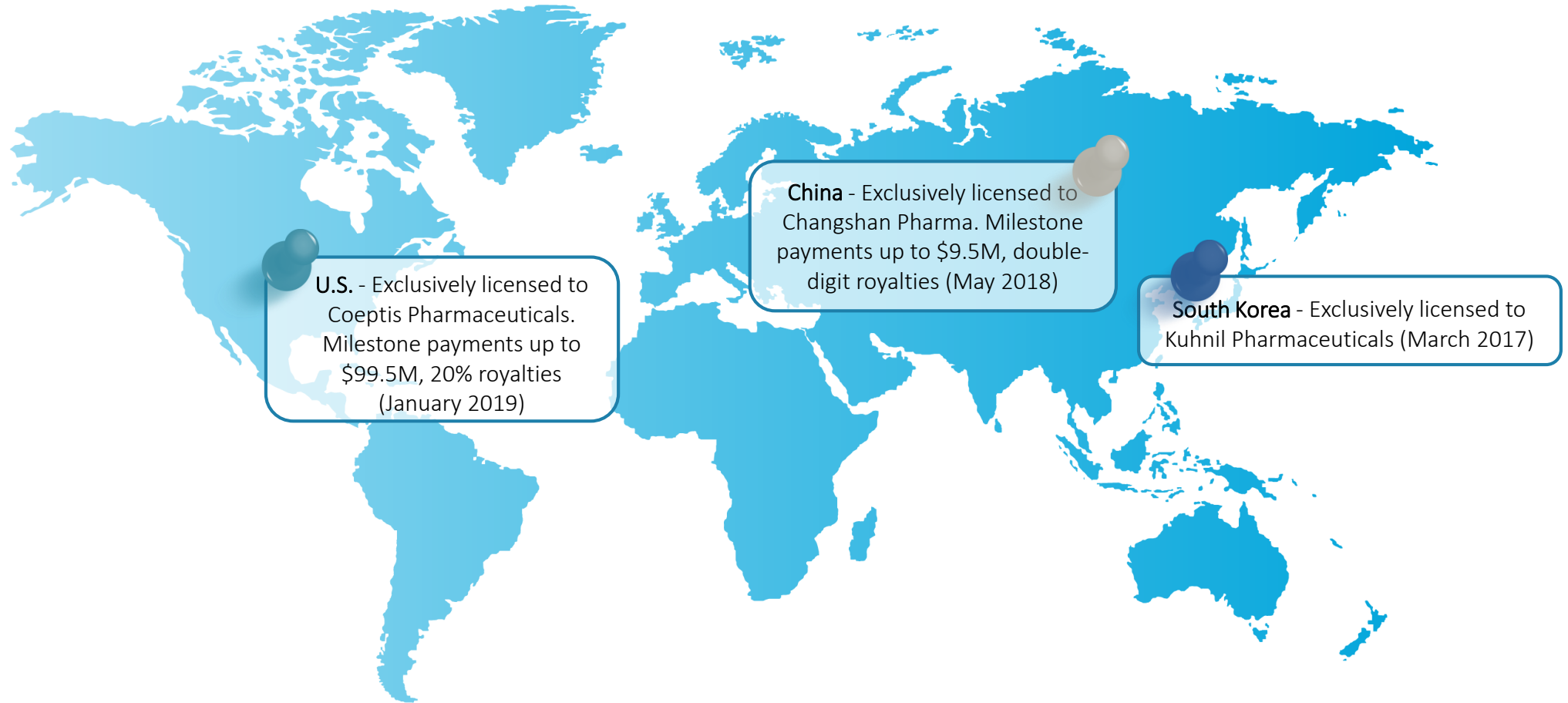
- 29% of U.S. adults older than 18
- 65% of U.S. adults older than 60

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



Consensi™
U.S. launch

NT-219
IND clearance

NT-219
Collaboration
agreement with
potential
strategic partner

NT-219
Initiation of
phase 1/2
clinical study

CM-24
IND
amendment
clearance

CM-24
Initiation of a phase
1/2 clinical study in
collaboration with
Bristol Myers-Squibb



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:
 - ✓ \$28M-36M of revenues from Consensi™ expected in 2020-2022
 - ✓ \$19M cash as of January 2019 (pro forma**)
- Current market cap. ~\$24M*

* As of April 30th , 2020

** including net \$3.5M + \$5.5M + \$5.8M raised in January 20, March 20 and April 20 financing transactions respectively



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

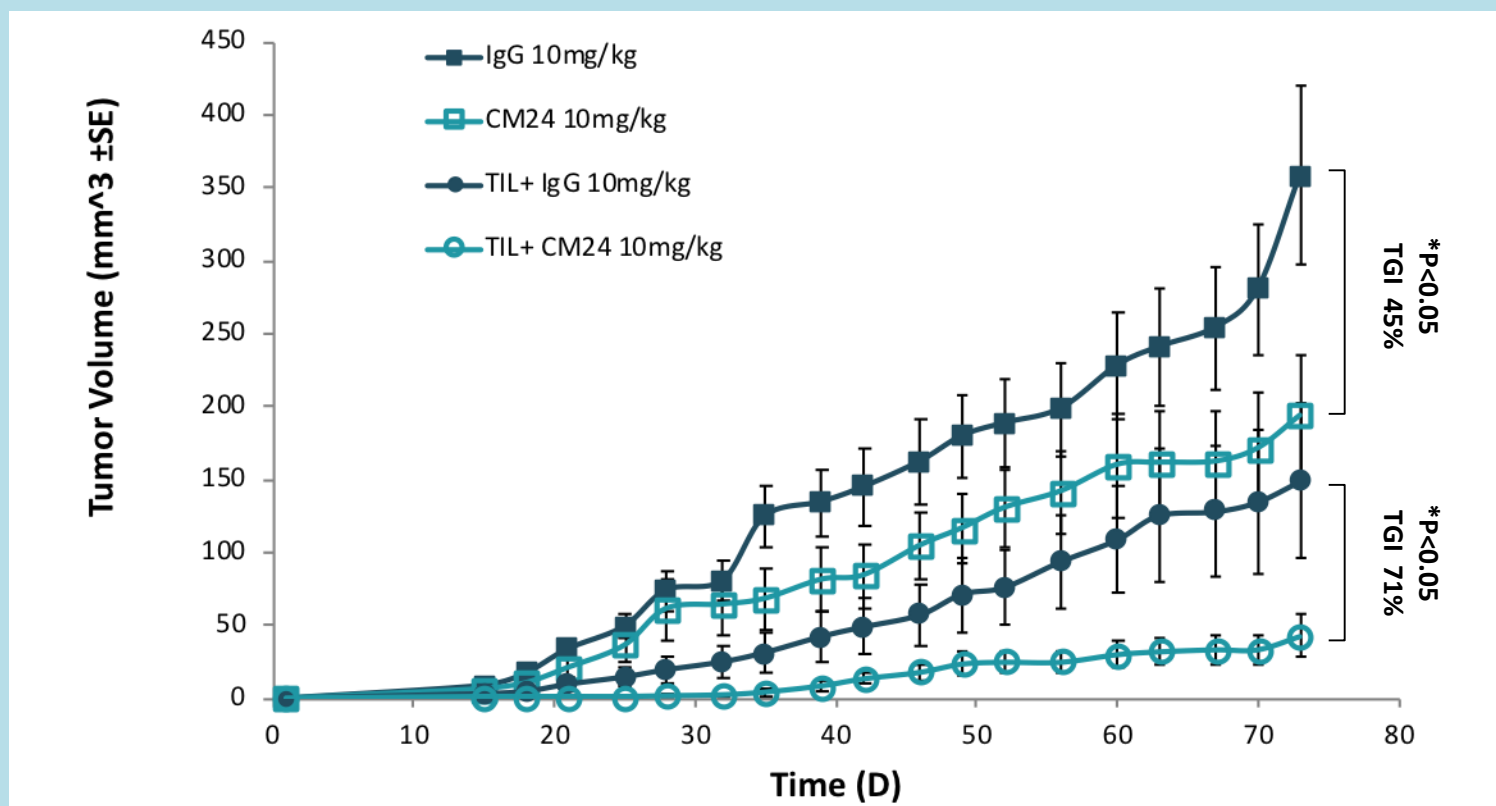


Appendix A - CM24



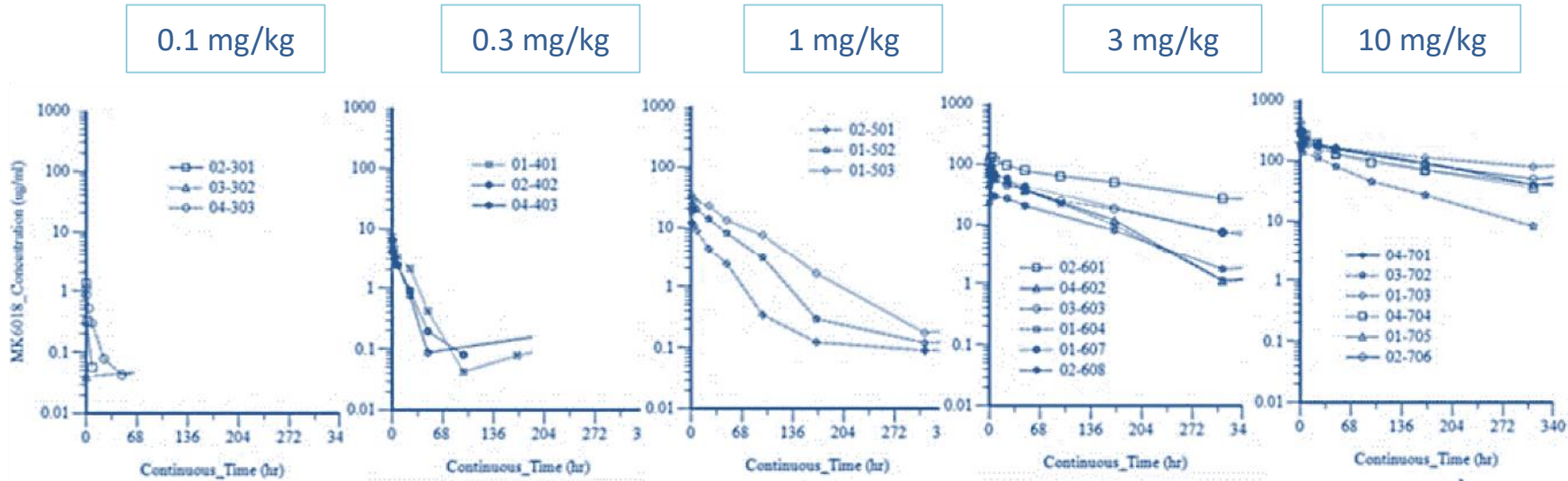
Inhibition of Melanoma Growth Following CM-24 and CM24 + TIL Treatment

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



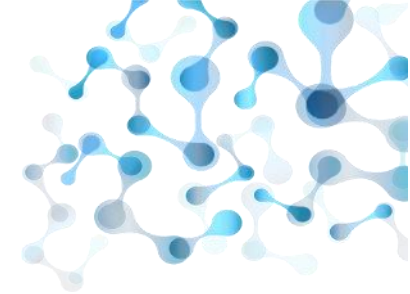
Phase 1 PK Data

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



Slower clearance with increasing dose

Higher half-life with increasing dose



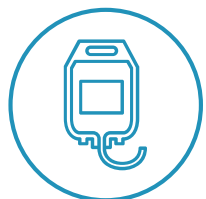
Appendix B - NT219

NT219 Re-sensitizes Tumors to Anti-PD1



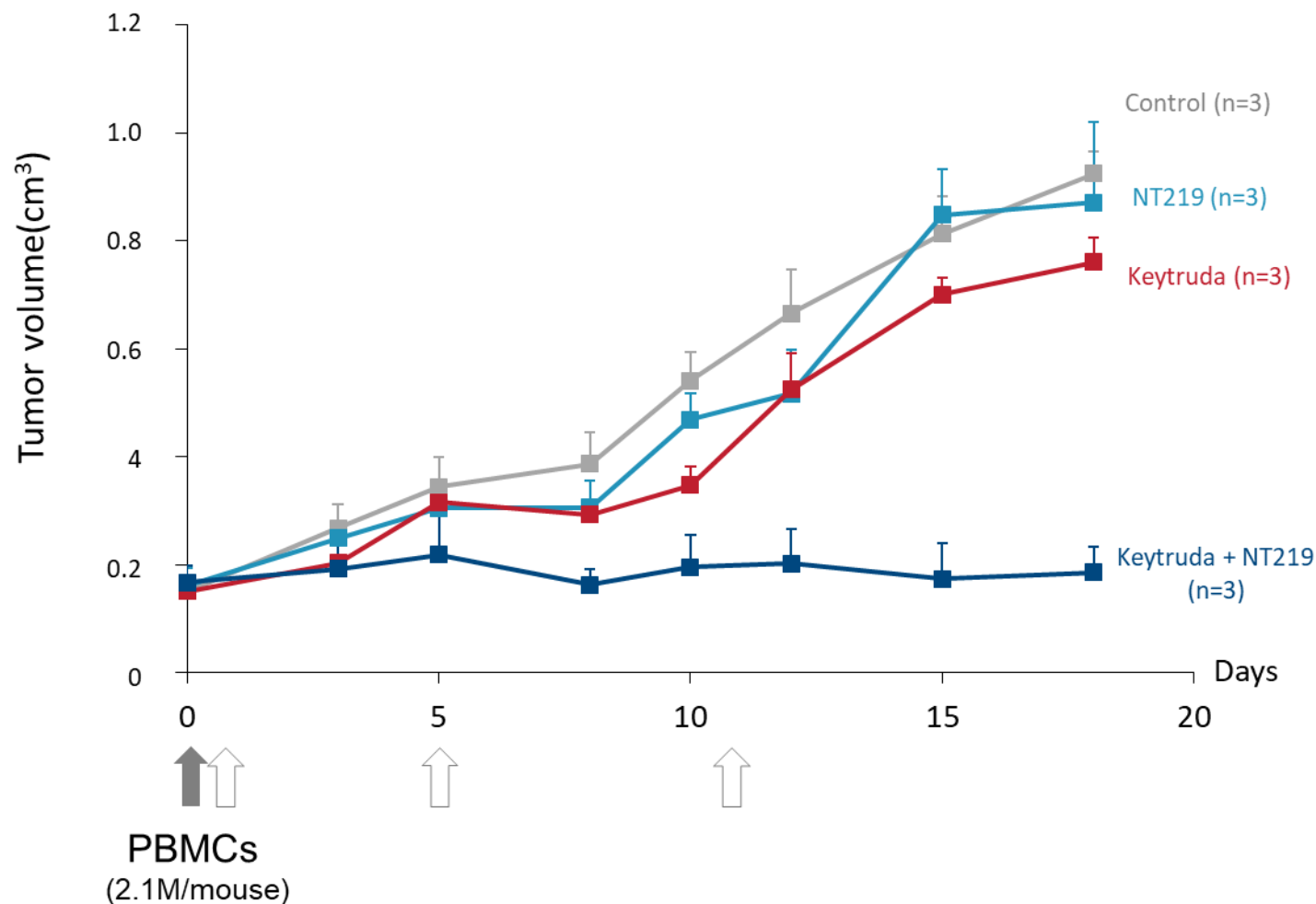
PDX model

**Humanized PDX of
Esophagus Cancer**

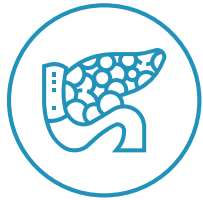


Drug

**Pembrolizumab
(Keytruda®)**

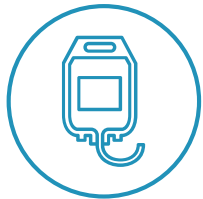


NT219 Overcomes Resistance to Gemcitabine in Pancreatic Cancer PDX Models



PDX model

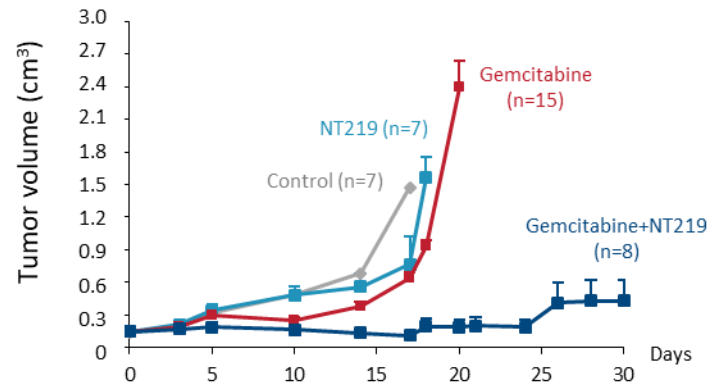
Pancreatic Cancer



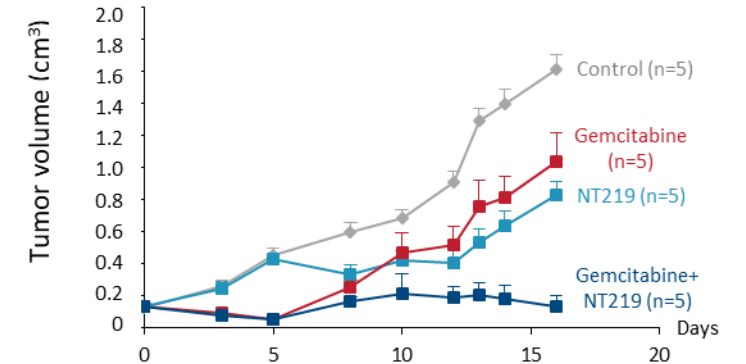
Drug

Gemcitabine (Gemzar®)

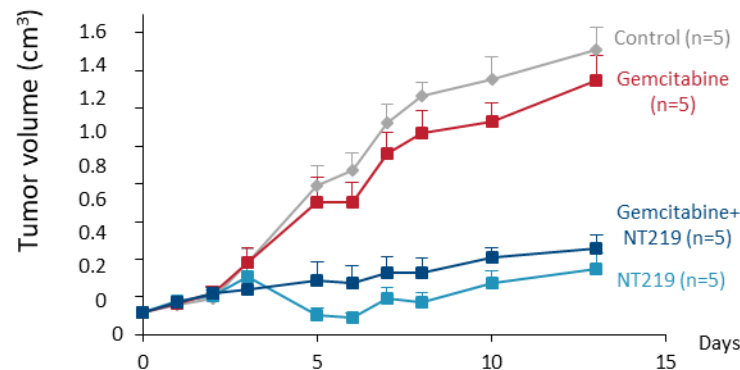
Pancreatic cancer (Patient A) PDX



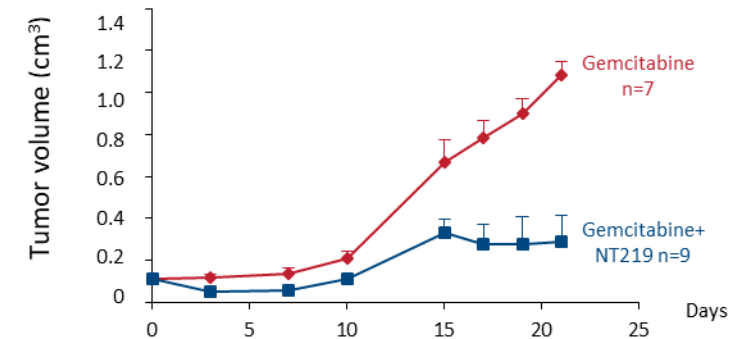
Pancreatic cancer (Patient B) PDX



Pancreatic cancer (Patient C) PDX



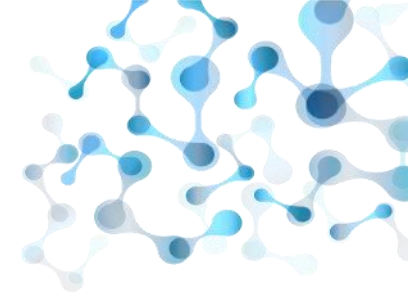
Pancreatic cancer (Patient D) PDX



Additional newly released data for NT-219 in reversing Pancreatic Cancer drug resistance is available on AACR PanCan poster:

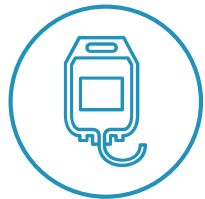
<http://kitovpharma.investorroom.com/index.php?s=151>

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



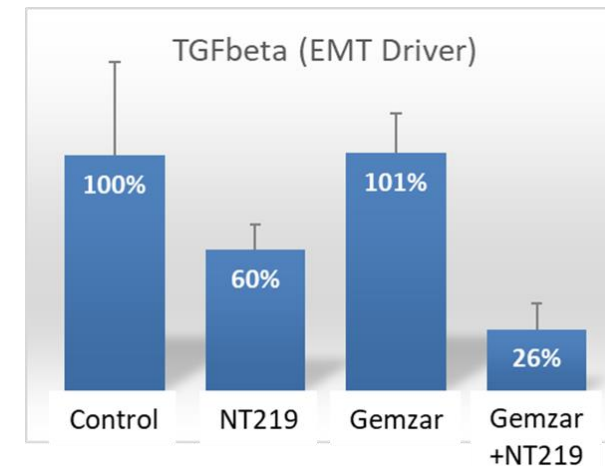
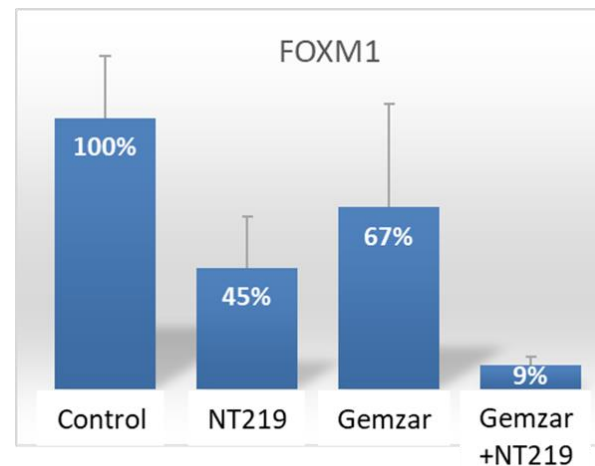
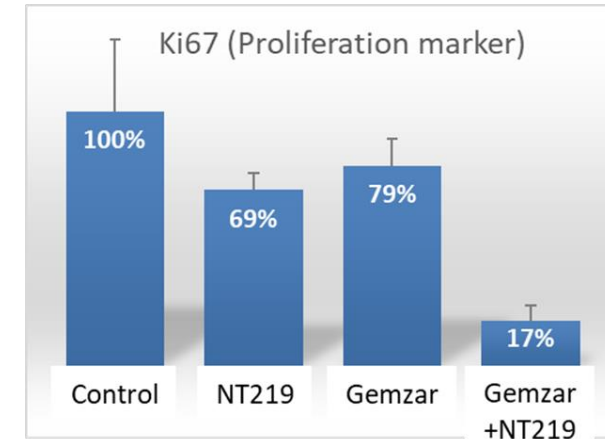
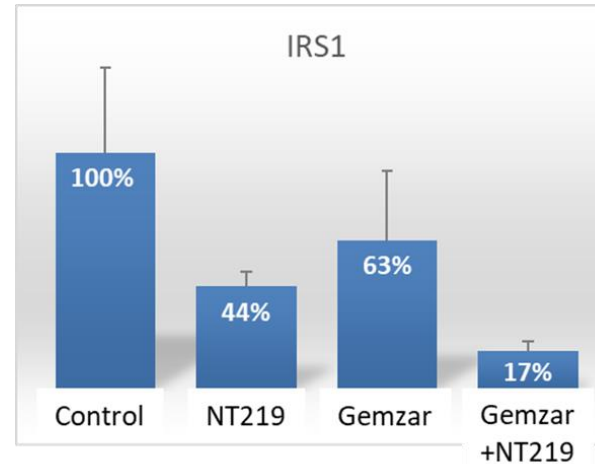
PDX model

Pancreatic Cancer



Drug

Gemcitabine (Gemzar®)



Selected Publications



Michael
Karin

Oncogene (2016) 35, 2634–2644
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www.nature.com/onc

ORIGINAL ARTICLE

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

E Sanchez-Lopez¹, E Flashner-Abramson², S Shalapour¹, Z Zhong¹, K Taniguchi^{1,3}, A Levitzki² and M Karin¹



Alexander
Levitzki

Oncogene (2016) 35, 2675–2680
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www.nature.com/onc

SHORT COMMUNICATION

Targeting melanoma with NT157 by blocking Stat3 and IGF1R signaling

E Flashner-Abramson¹, S Klein¹, G Mullin¹, E Shoshan², R Song², A Shir¹, Y Langut¹, M Bar-Eli², H Reuveni^{1,3,4,5} and A Levitzki^{1,4}



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,*}, Efrat Flashner-Abramson², Lilach Steiner^{1,2}, Kirill Makedonski^{1,2}, Renduo Song³, Alexei Shir¹, Meenhard Herlyn⁴, Menashe Bar-Eli³, and Alexander Levitzki^{2*}



Michael
Cox

Published OnlineFirst September 29, 2014; DOI: 10.1158/1535-7163.MCT-13-0842

Small Molecule Therapeutics

Molecular
Cancer
Therapeutics

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

Naokazu Ibuki^{1,2}, Mazyar Ghaffari^{1,3}, Hadas Reuveni^{4,5}, Mitali Pandey¹, Ladan Fazil¹, Haruhito Azuma², Martin E. Gleave^{1,6}, Alexander Levitzki³, 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

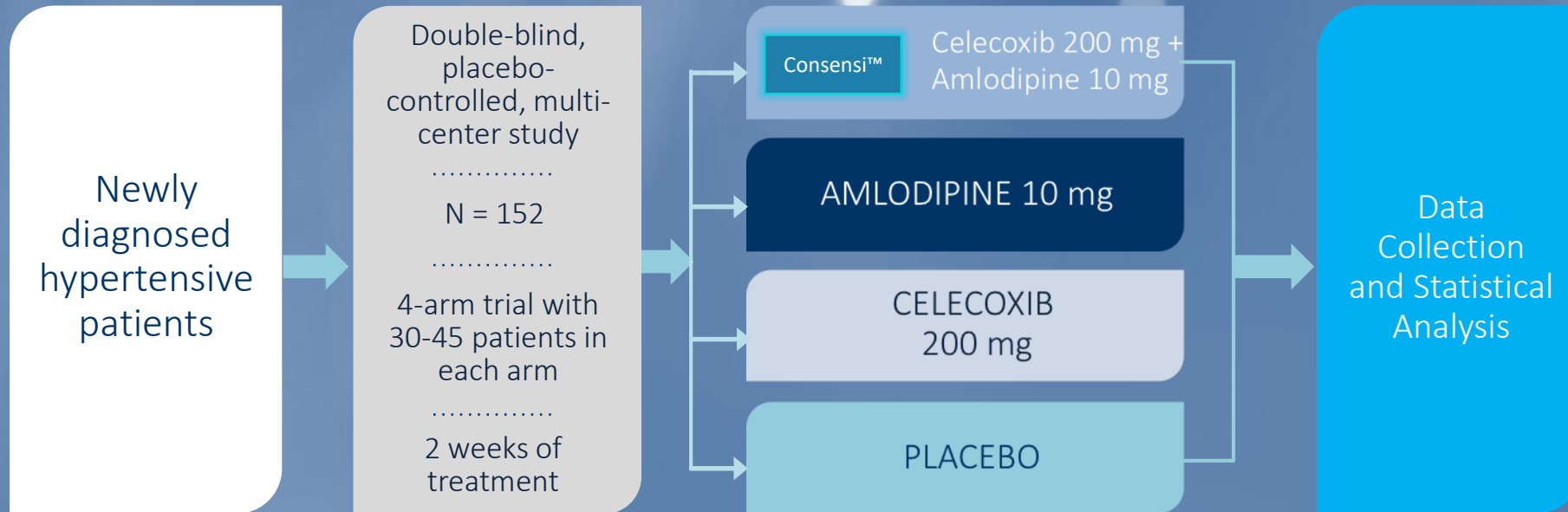
- **CELEBREX, may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal. All NSAIDs may have a similar risk. This risk may increase with duration of use. Patients with cardiovascular disease or risk factors for cardiovascular disease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

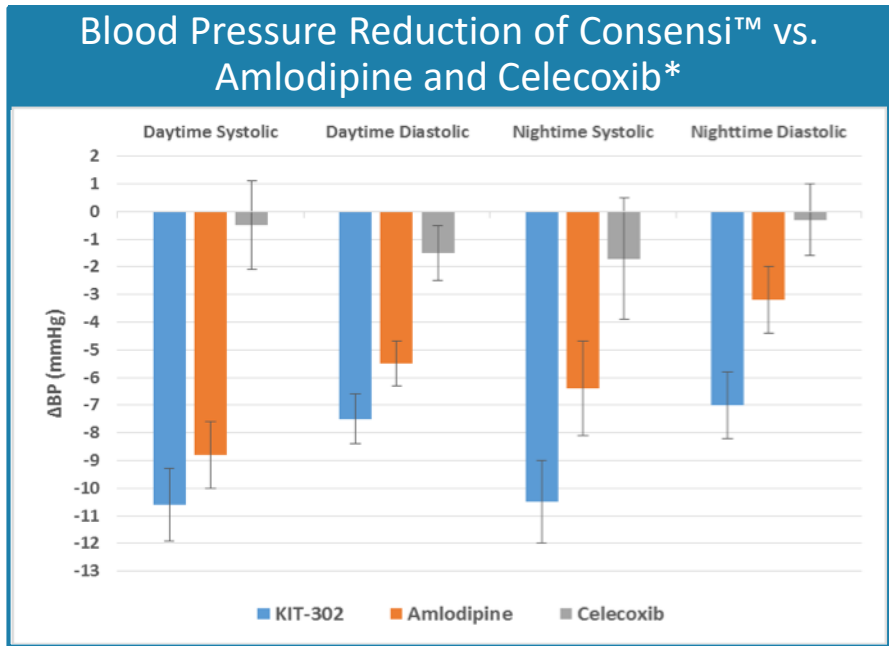


Primary endpoint

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 $\mu\text{mol/L}$	-2.55 $\mu\text{mol/L}$
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