tiziana

LIFE SCIENCES

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Corporate Presentation

www.tizianalifesciences.com **NASDAQ: TLSA** **LSE: TILS**

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Investment Highlights

- **Novel platform technologies that enable oral, nasal and subcutaneous administration of monoclonal antibodies** (mAbs) create two opportunities:
  1. **Wholly owned assets** targeting known mechanisms of action that facilitate topical effects, maximizing efficacy
  2. **Licensing reformulations** of approved or development stage products to other companies for royalty stream
- Wholly owned assets have multiple upcoming milestones
  - **Foralumab**, a fully human anti-CD3 mAb, in Phase1b/Phase 2 development for Crohn's Disease (oral administration) and Phase 2 for progressive Multiple Sclerosis (nasal administration)
    - Crohn's and pro-MS interim data available in 1H 2022, anticipated trial completion in 2H 2022.
  - **TZLS-501**, a fully human anti-IL6 receptor mAb, for pulmonary diseases.
    - Anticipated IND submission 4Q 2021, followed by Phase 1 SAD study
  - **Milciclib**, a pan-CDK (cyclin dependent kinase) inhibitor for hepatocellular carcinoma (HCC) and solid tumors
    - Completed Phase 2 trial in advanced HCC patients. The next trial is being planned
    - A potential Phase 2 trial in KRAS+ NSCLC is being planned

Tiziana Platform Enables Oral, Nasal and Subcutaneous Administration of Antibodies

Most antibodies require IV administration currently

- **Costly and burdensome**
- **Systemic treatment requires higher doses and toxicity**

tiziana
platform enables…

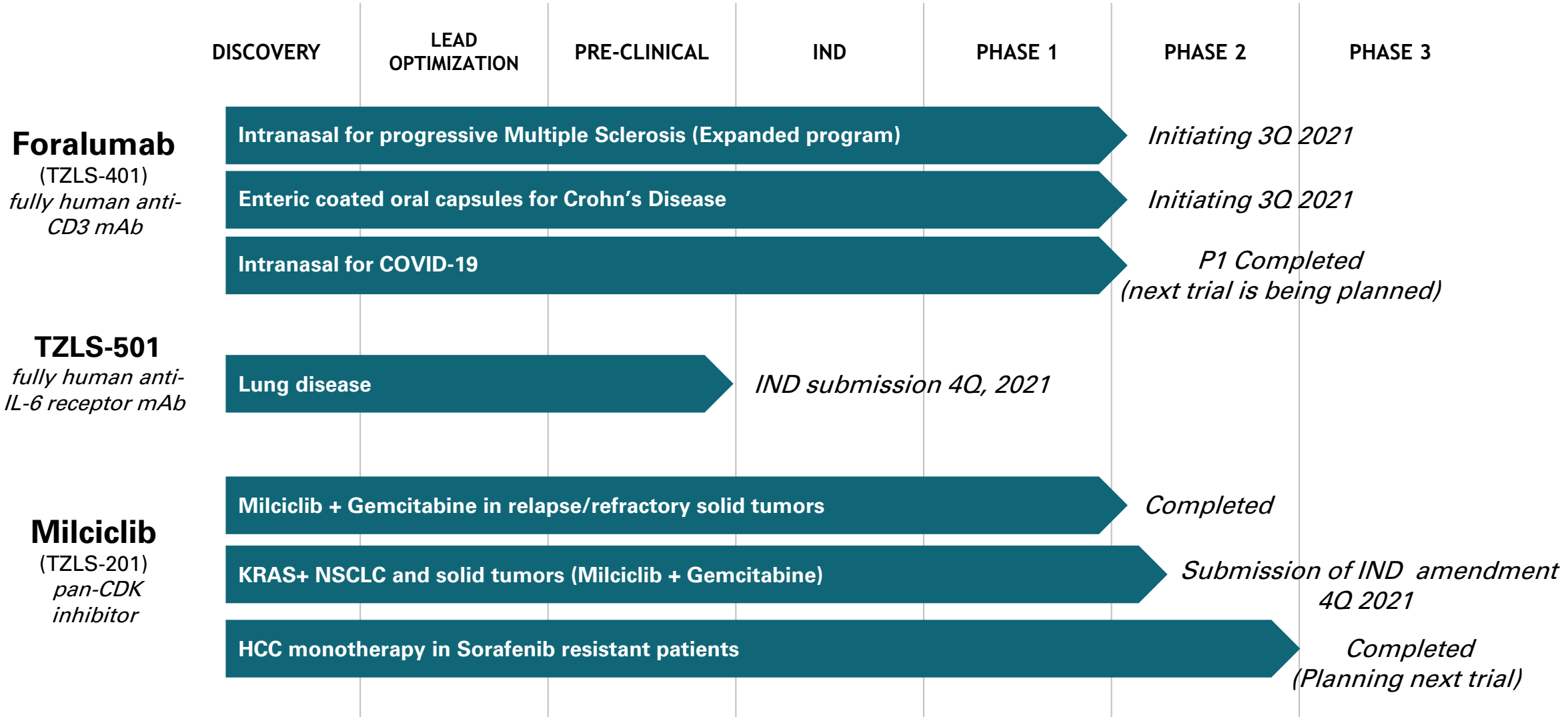
Oral administration

Nasal administration

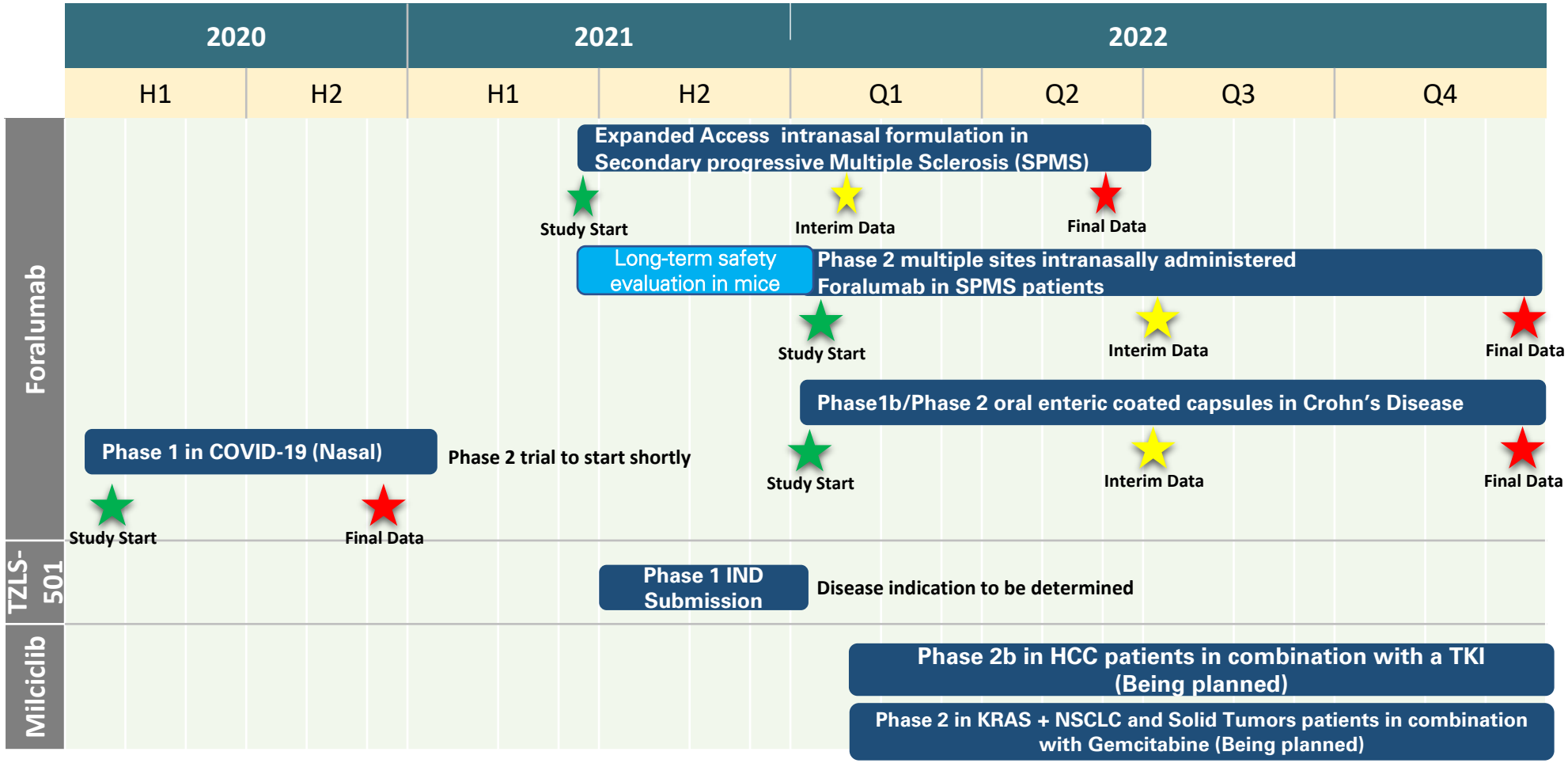
SC Safety studies to begin shortly

- **Ease of use and home administration significantly decreases patient burden**
- **Reduced costs due to lack of infusion**
- **These alternative delivery methods can minimize toxicity and concentrate distribution to target tissues**

Pipeline


DISCOVERY
LEAD OPTIMIZATION
PRE-CLINICAL
IND
PHASE 1
PHASE 2
PHASE 3
Foralumab
(TZLS-401)
fully human anti-CD3 mAb
Intranasal for progressive Multiple Sclerosis (Expanded program)
Initiating 3Q 2021
Enteric coated oral capsules for Crohn's Disease
Initiating 3Q 2021
Intranasal for COVID-19
P1 Completed
(next trial is being planned)
TZLS-501
fully human anti-IL-6 receptor mAb
Lung disease
IND submission 4Q, 2021
Milciclib
(TZLS-201)
pan-CDK inhibitor
Milciclib + Gemcitabine in relapse/refractory solid tumors
Completed
KRAS+ NSCLC and solid tumors (Milciclib + Gemcitabine)
Submission of IND amendment 4Q 2021
HCC monotherapy in Sorafenib resistant patients
Completed
(Planning next trial)

Upcoming Milestones



Foralumab

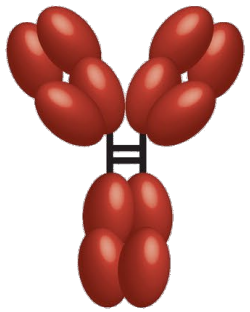
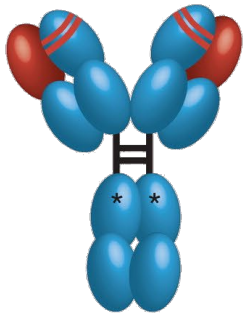
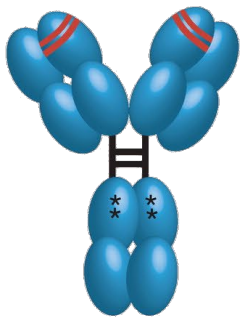
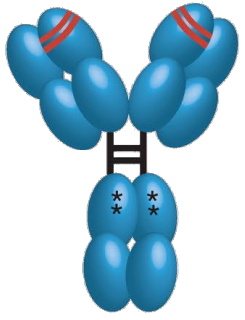
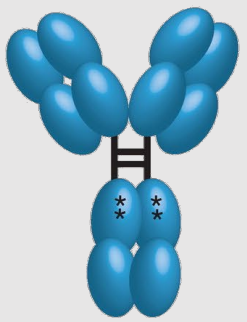
Foralumab, a Fully Human anti-CD3 mAb in Phase 1b/Phase 2

- Foralumab is a fully human IgG1 anti-CD3 mAb that can be delivered via oral, nasal and subcutaneous administration.
- Foralumab is the only fully human anti-CD3 mAb currently in clinical development.
- CD3 target has been validated by Muromonab (OKT3), an IgG2a fully mouse mAb that was approved by the FDA for solid organ transplantation immunosuppression.
- Tiziana has completed Phase I trials with nasal and oral administration, respectively.
- Currently in Phase 1b/Phase 2 development for Crohn's Disease and Phase 2 for progressive Multiple Sclerosis

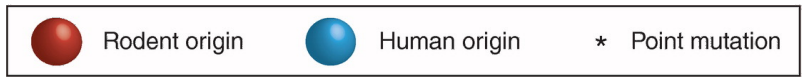
- Licensed from Novimmune, which studied IV Foralumab in a Phase I and two Phase II clinical trials, totaling 68 patients:
  - *NCT00630643, NCT00805909*
- Although it was generally well tolerated at doses of up to 1mg/day and a trial in Crohn's patients demonstrated a reduction in Crohn's Disease Activity Index (CDAI) scores, the therapeutic index with IV administration was suboptimal.
- Oral delivery to the gut for GI indications and intranasal administration for CNS indications maximizes therapeutic activity in affected organs while drastically reducing systemic exposure and toxicity

Foralumab is the Only Fully Human Anti-CD3 mAb in Clinical Trials

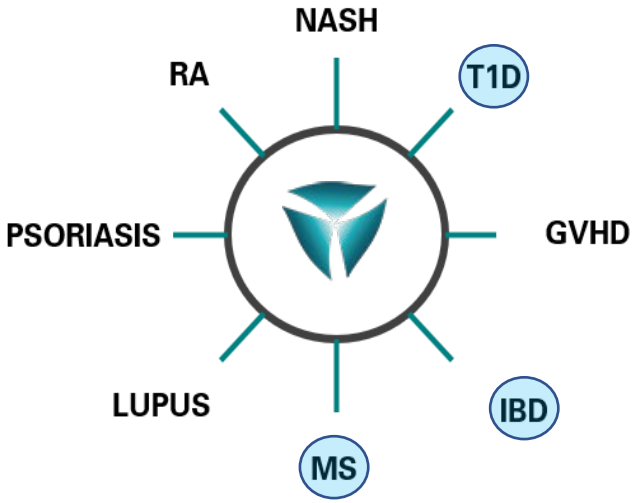
CD3-specific Monoclonal Antibodies In Clinical Development

OKT3 Muromonab*	ChAglyCD3 Otelixizumab	hOKT3γ1(Ala-Ala) Teplizumab	Nuvion Visilizumab	**Foralumab**
				
IgG2a	IgG1 N297/A	IgG2 L234/A, L235A	IgG2 L234/A, V237/A	IgG1 L234/A, V335E
Fully Mouse	Chimeric & Humanized	Humanized	Humanized	Fully Human

*Approved by the FDA for solid organ transplantation immuno-suppression



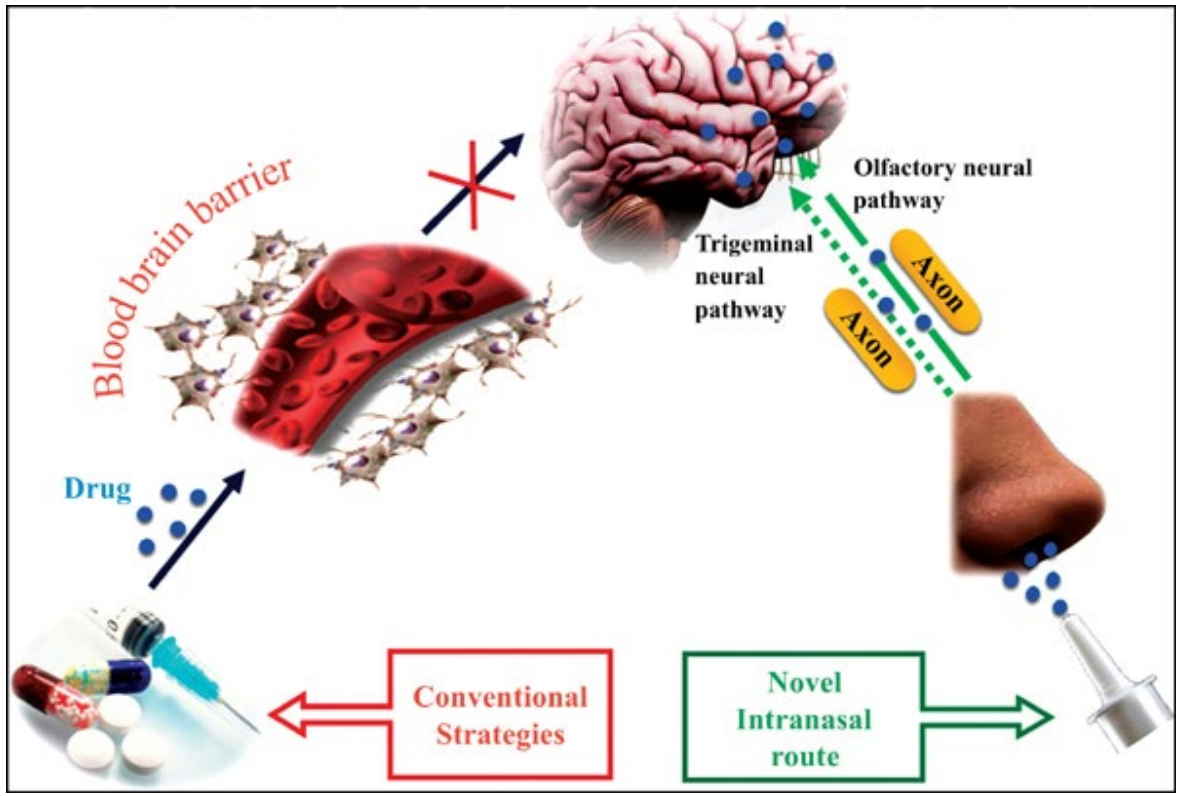
Oral and Nasal Administration Market Opportunities

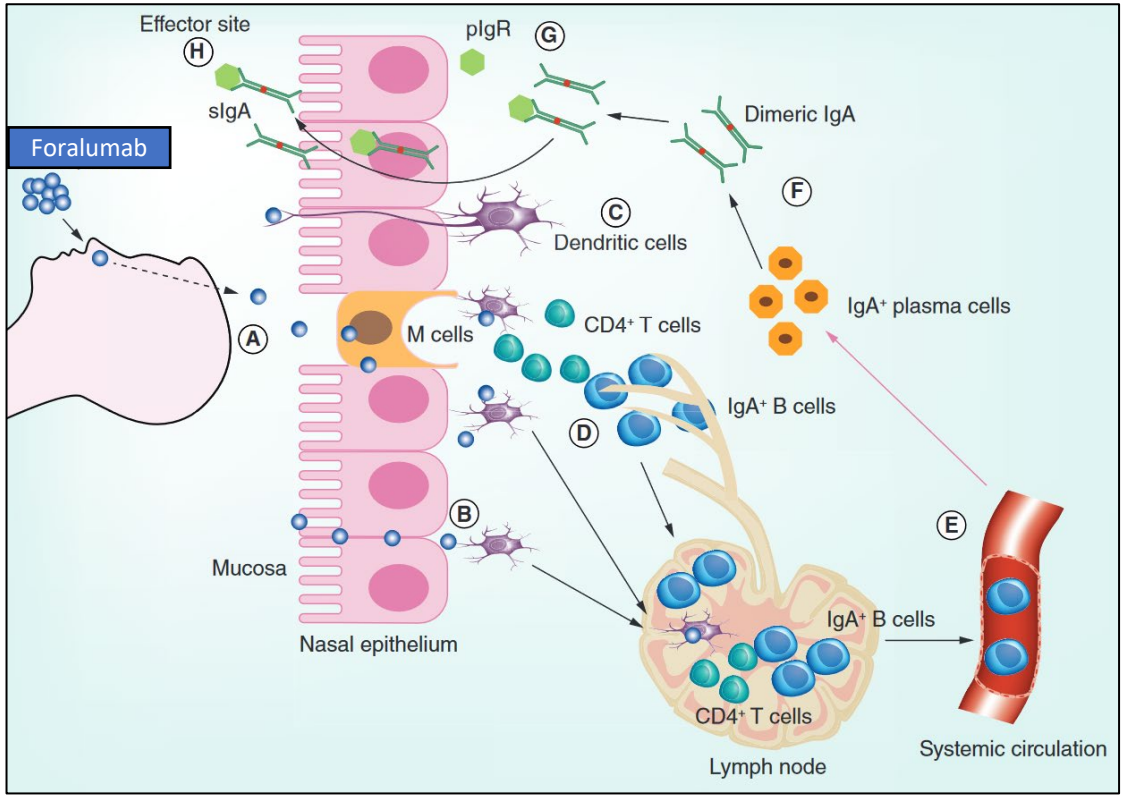


Current focus

Adapted from: Kuhn, Chantal, and Howard L. Weiner. "Therapeutic anti-CD3 monoclonal antibodies: from bench to bedside." Immunotherapy 8.8 (2016): 889-906.

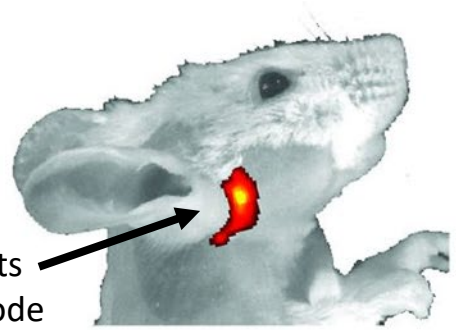
Nasal Administration of Anti-CD3 mAb May Work Via Activation of Mucosal Immunity in Cervical Lymph Node

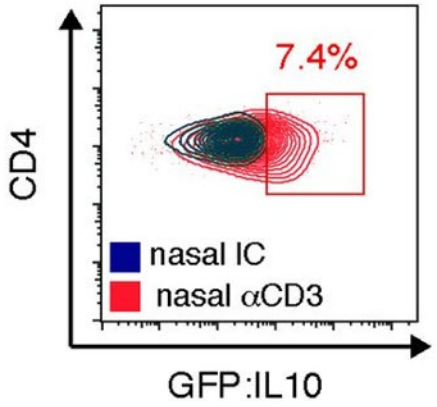


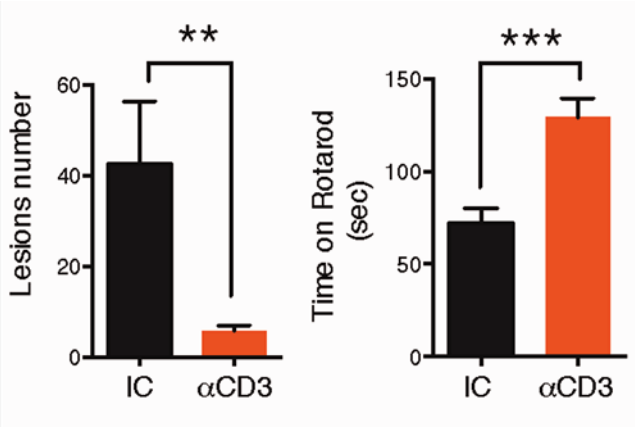


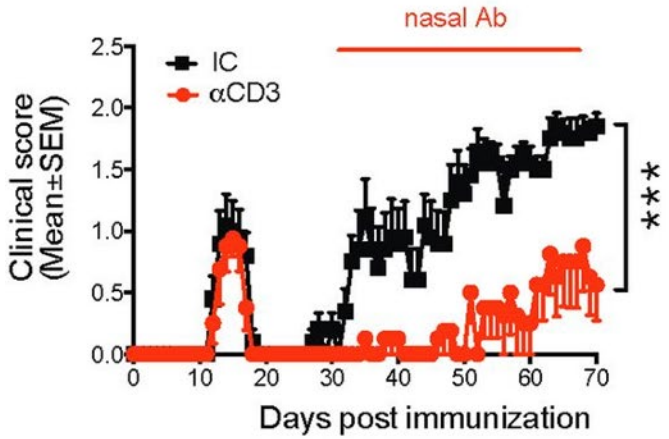
Adapted from: Marasini, Nirmal, Mariusz Skwarczynski, and Istvan Toth. "Intranasal delivery of nanoparticle-based vaccines." Therapeutic Delivery 8.3 (2017): 151-167.

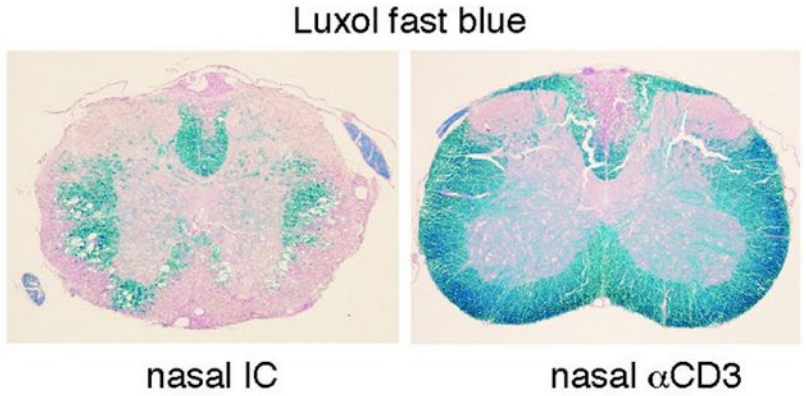
Nasally Administered Anti-CD3 mAb Suppress Progressive MS

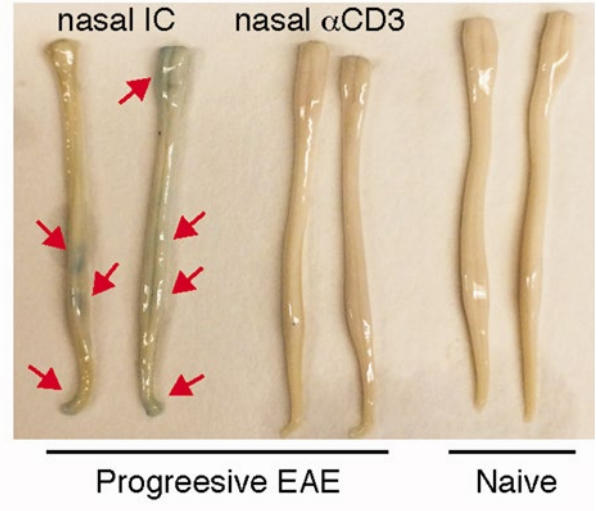












Mayo, Lior, et al. "IL-10-dependent Tr1 cells attenuate astrocyte activation and ameliorate chronic central nervous system inflammation." *Brain* 139.7 (2016): 1939-1957.

Nasally Administered Foralumab in Phase II for Progressive Multiple Sclerosis

- Phase I trial conducted at Harvard Brigham and Women's Hospital completed in July 2019.
  - Dose-ranging, double-blind, placebo-controlled study in healthy subjects.
  - Foralumab was administered nasally at 10, 50 and 250 µg/day for 5 consecutive days using a hand-held spray device (6 active and 3 placebo patients in each dose level).
- Foralumab was well-tolerated with no drug-related toxicities.
- 50-µg dose upregulated T regulatory cells (Tregs), stimulated the anti-inflammatory cytokine IL-10, and suppressed the pro-inflammatory cytokine IFN-γ
  - Tregs are capable of crossing Blood Brain Barrier to suppress inflammation commonly associated with neurodegenerative diseases, including Multiple Sclerosis

Next clinical trial

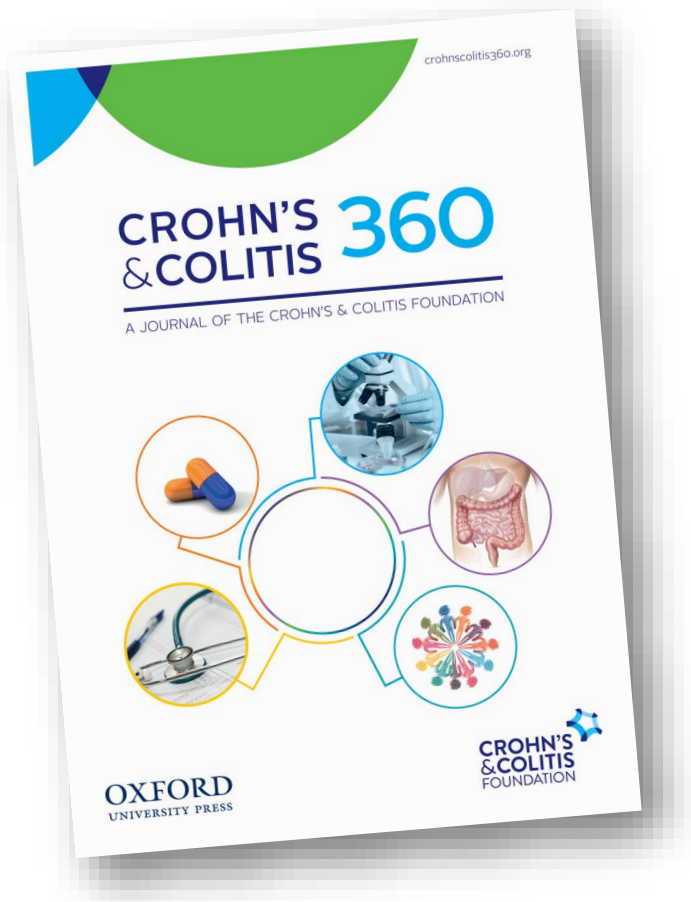
- FDA allowed an expanded program with nasally administered foralumab in SPMS
- Long-term safety study in mice to start shortly
- Phase 2 trial to begin following safety evaluation. Proposed clinical trial design: 60 patients, multi-centered, placebo controlled
  - Three arms: Placebo, 50 ug and 100 ug nasal Foralumab
  - Lead site at Harvard Brigham and Women's Hospital
- Primary endpoint: Safety and Tolerability
- Secondary endpoints: Cognitive behavior, Tregs, microglial suppression and biomarkers

Anti-CD3 mAbs Have Been Clinically Validated in Ulcerative Colitis

- Oral administration of anti-CD3 mAbs has been clinically validated in patients with inflammatory bowel disease
- Investigator initiated trial by Dr. Scott Snapper at Harvard.
- Patients with moderate-to-severe ulcerative colitis received oral OKT3

KEY FINDINGS

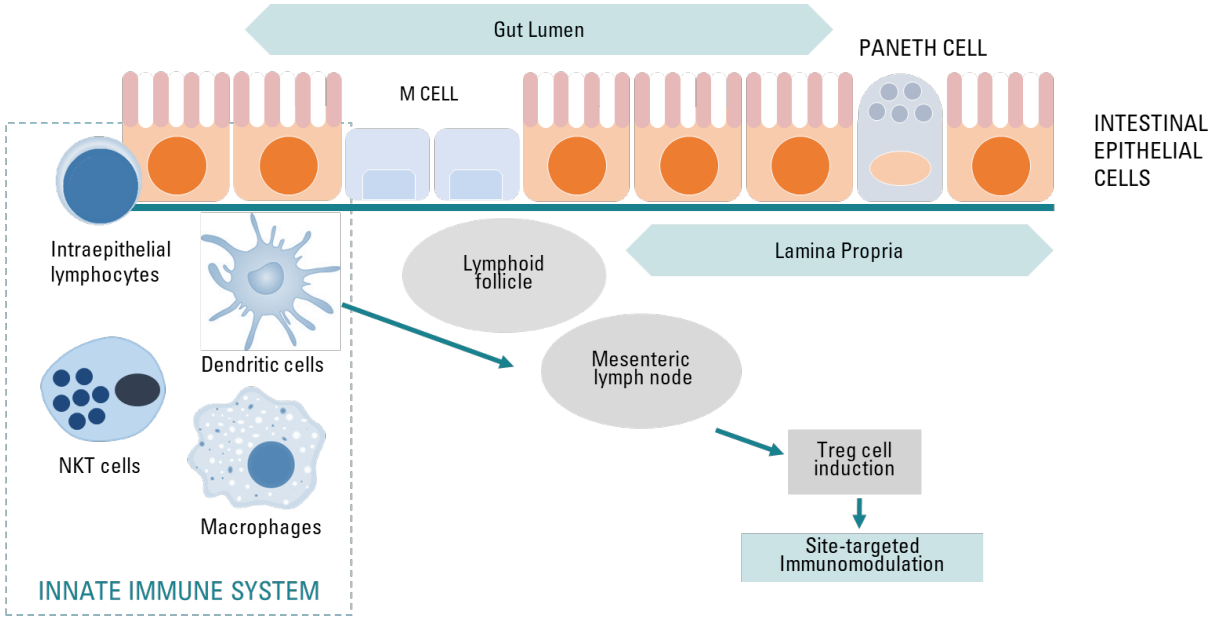
1. Biologic response of increased proliferation and anti-inflammatory gene expression profile in peripheral blood mononuclear cells
2. 3 of 6 patients had a clinical response including one patient in clinical remission
3. Treatment was well-tolerated with no serious treatment-related adverse events



* Boden, E. K., Canavan, J. B., Moran, C. J., McCann, K., Dunn, W. A., Farraye, F. A., Ananthakrishnan, A. N., Yajnik, V., Gandhi, R., Nguyen, D. D., Bhan, A. K., Weiner, H. L., Korzenik, J. R., Snapper, S. B. Immunologic alterations associated with oral delivery of anti-CD3 (OKT3) monoclonal antibodies in patients with moderate-to-severe ulcerative colitis. Crohn's & Colitis 360 (2019). 183: 240-246.

Orally Administered Foralumab in Phase II for Crohn's Disease

- Phase 1 trial conducted at Brigham and Women's Hospital completed December 2019
  - Single ascending dose, double-blind, placebo-controlled study in healthy subjects
  - Foralumab administered at 1.25, 2.5 and 5.0 mg/dose as stabilized powder formulation in enteric-coated capsules
- Well-tolerated at all doses tested and no drug-related safety issues observed, including toxicities associated with IV administration of anti-CD3 mAbs.



Next clinical trial

- Phase 1b trial with 'Take Home' oral capsules once a day dosing for 14 days.
- Open label adaptive design with dosing of 0.5, 1.25. 2.5 and 5.0 mg for 14 days.
- Primary endpoint: Safety and tolerability
- Secondary end points: mucosal healing, PK, ADA and biomarkers for assessment of clinical responses and MOA
- If treatment is well tolerated then start Phase 2 trial

COVID-19 Programs

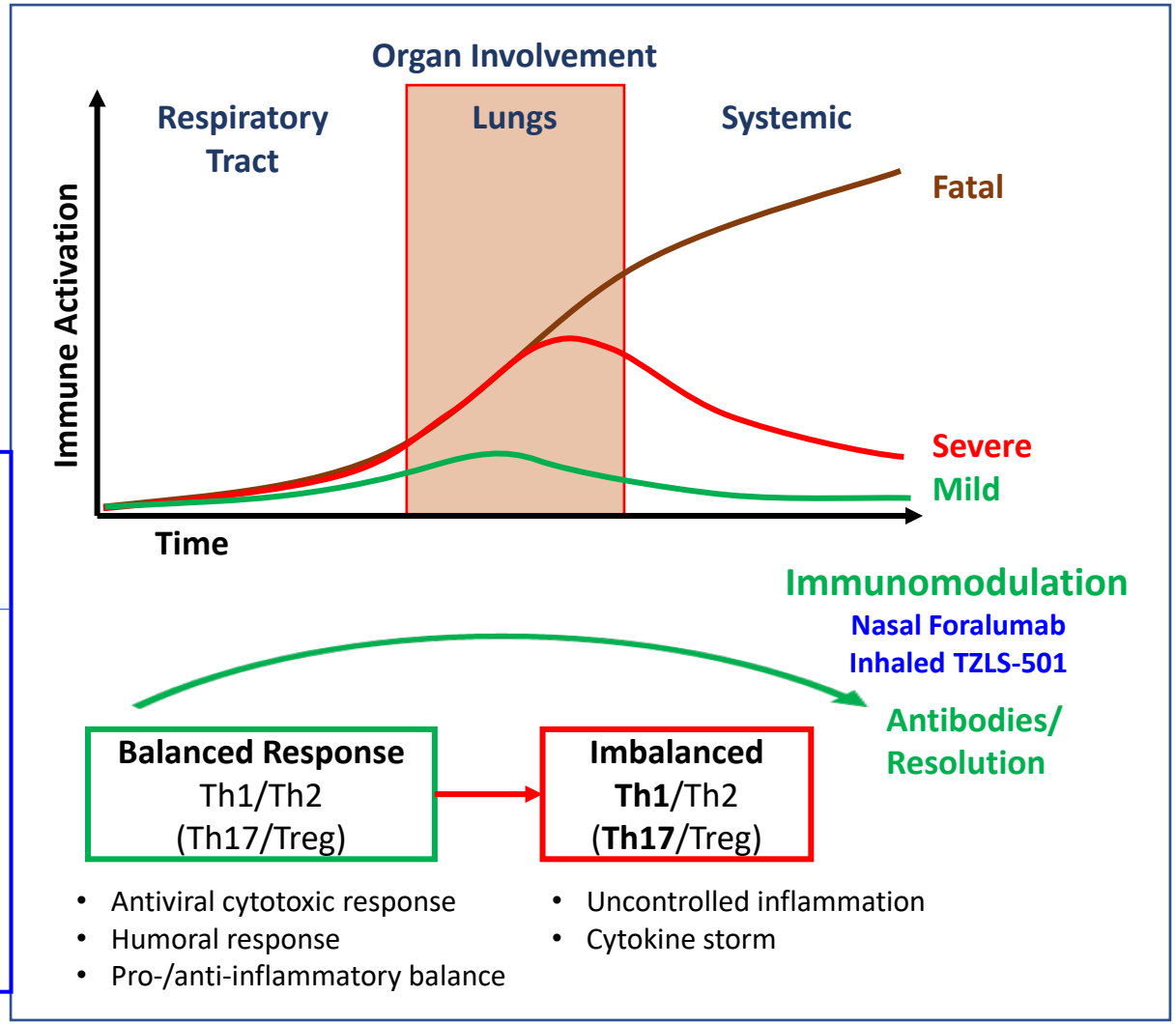
Nasally administered Foralumab

Nasal Administration of Foralumab for Mild to Moderate COVID-19

- The first validation that nasally administered Foralumab is well-tolerated and the treatment provides clinical benefits

- Three arms: Treatment for 10 days
  - Control (n-16)
  - Nasal Foralumab 100 ug/day (n=12)
  - Nasal Foralumab 100 ug/day + Oral Dexamethasone (6 mg/day/3 days) (n=11)

Cohort (evaluable patients)	Lung CT Scan (% Improvement)	Cytokine IL-6 (% Reduction)	C-Reactive Protein (% Reduction)
Control (n=14)	**43**	**37**	**40**
Foralumab + Dexa (n=12)	**75**	**41**	**55**
Foralumab (n=10)	**80**	**69**	**85**

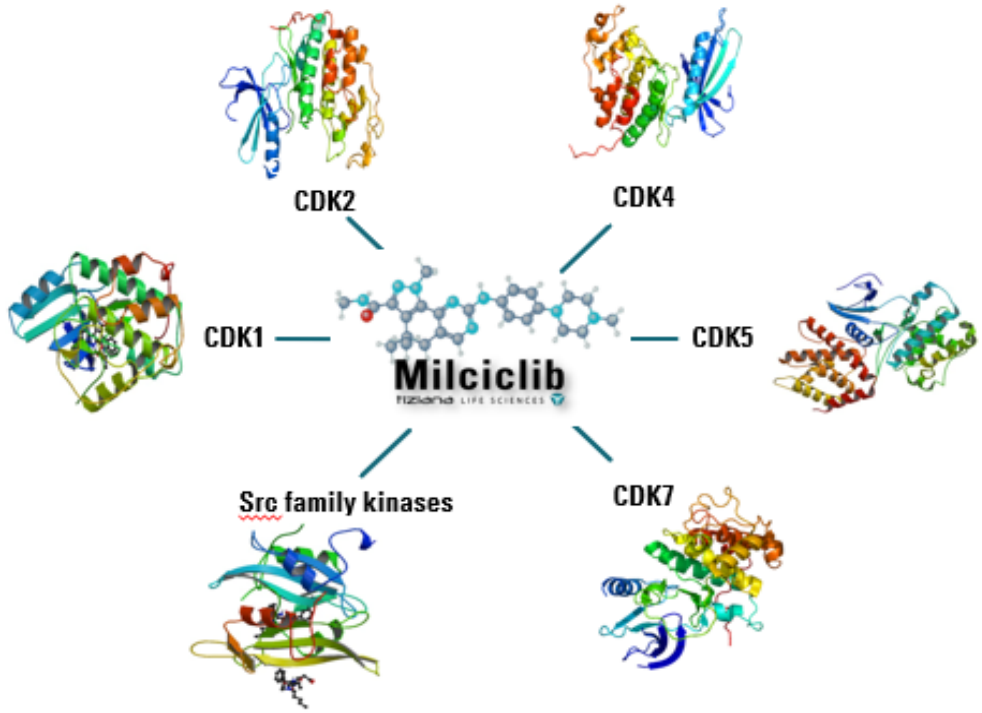


Strong positive topline data reported Feb 2, 2021. Next trial is being planned

Milciclib

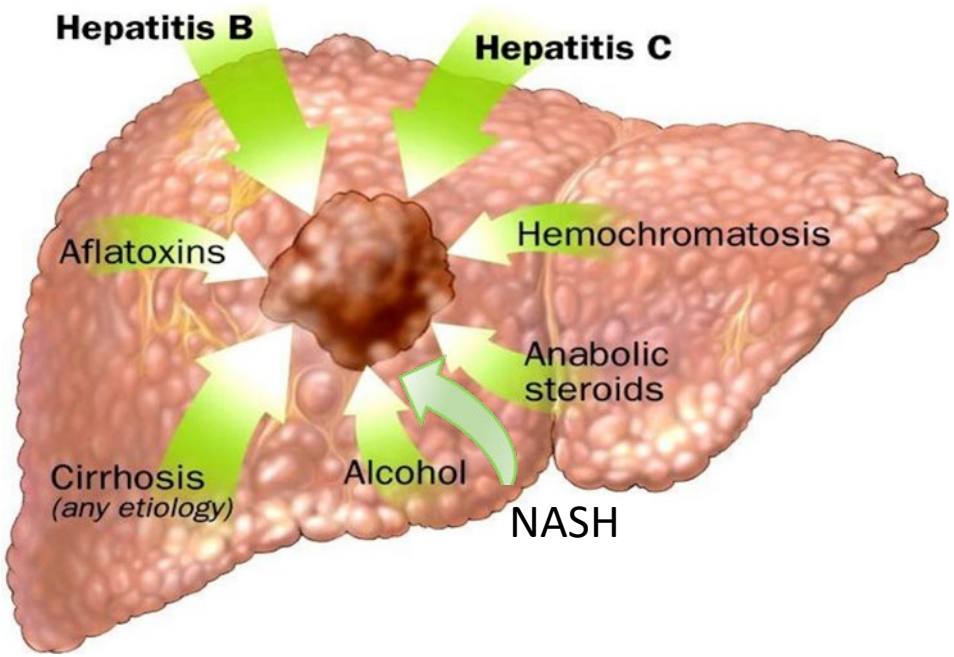
Milciclib (TZLS-201), a Small Molecule Pan-CDK Inhibitor for Solid Tumors

- Milciclib (TZLS-201) is an orally-bioavailable small molecule pan-CDK inhibitor in Phase II development for solid tumor indications, including HCC and NSCLC
- Inhibits kinases that are key signaling pathways for hepato-carcinogenesis and associated with cancer cell growth, including CDK1, CDK2, CDK4 CDK5, CDK7 and src-family kinases
- Completed multiple clinical trials meeting primary and secondary clinical endpoints.
  - Completed Phase IIa in sorafenib-resistant HCC
  - Completed two Phase II trials in thymoma and thymic carcinoma
  - Well tolerated and expected to have an improved toxicity profile over the current standard of care
- Orphan Drug Designation granted in US and EU



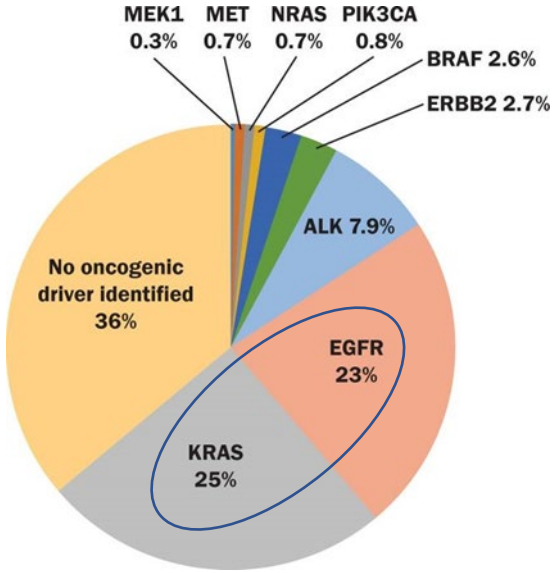
Milciclib Targets Multiple Pathways in HCC and NSCLC

- HCC is a complex and heterogenous cancer associated with multiple etiological factors that may benefit from a broad-spectrum approach



Noha E. Ibrahim, Wael M. Aboulthana, Ram Kumar Sahu. Hepatocellular Carcinoma: Causes and Prevention. UKJPB. 2018; 6(5): 48-55.

- NSCLC is a complex and heterogenous cancer with multiple genetic mutations
- K-RAS and EGFR mutations predominate in NSCLC
- K-RAS ^{G12C} mutant NSCLC remains an unmet medical need



Sholl, Lynette M., et al. "Multi-institutional oncogenic driver mutation analysis in lung adenocarcinoma: the lung cancer mutation consortium experience." *Journal of thoracic oncology* 10.5 (2015): 768-777.

Phase 1 Study of Milciclib + Gemcitabine in Refractory Solid Tumors

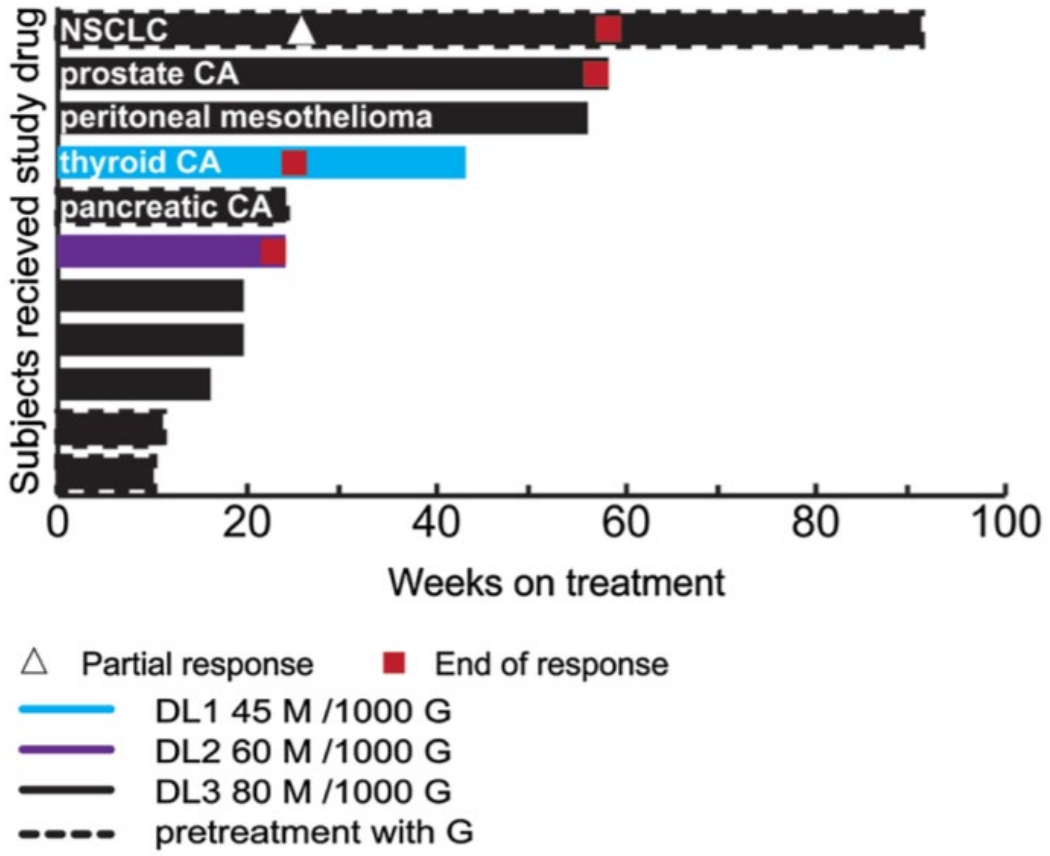
Trial design:

- 16 patients with refractory solid tumors treated with oral milciclib at three dose levels (45, 60, and 80 mg/m2/day) with a fixed dose of IV gemcitabine (1000 mg/m2/day).

Results

- Milciclib was well-tolerated with manageable side effects
- Overall response rate was 36%
- Clinical activity was observed in patients who were non-responders to all standard therapy
- among 14 evaluable patients, one NSCLC patient showed partial response and 4 patients (one each with thyroid, prostatic, pancreatic carcinoma and peritoneal mesothelioma) showed long-term disease stabilization (>6-14 months).
- Recommended Phase 2 dose (RPD) found to be 80mg/m2/day

Next trial in KRAS+ NSCLC patients is being planned



Swimmerplot showing treatment duration. Tumor type was indicated for patients having a prolonged stable disease or a partial response. M Milciclib; G gemcitabine.

Cancer Chemotherapy and Pharmacology, June 2017, 79(6), 1257-1265

Milciclib Phase 2a Trial in Sorafenib-resistant HCC

Trial design:

- Dosing: Oral 100 mg/day, consecutive 4 days a week in a 4-week cycle for 6 months
- Population: 30 sorafenib-resistant HCC patients
- Primary end point: safety
- Secondary end points: PFS, ORR & TTP
- Exploratory: AFP and miRNA profiling

Status: Complete with data from 28 out of 31 evaluable

- 14 patients completed treatment as per protocol
- Nine patients were approved for compassionate use.
  - Seven patients extended treatment until 9, 9, 10, 11, 13, 13 and 16 months.
  - **Two patients currently continuing compassionate use in ongoing treatment at 20 months**
- **Treatment was well-tolerated and adverse events were manageable with no drug related deaths in the trial**
- **Median time to progression was 5.9 months**
- **Stabilized Disease (SD): 61%**
- **Clinical Benefit Response: 64%**

Next trial with combination of Milciclib with a TKI patients in Asian countries is being explored

Intellectual Property Portfolio

Asset	Subject	Priority	Status	Expires	Jurisdiction
Foralumab (TZLS-401) *fully human anti-CD3 mAb*	Methods of Use (Autoimmune or Inflammatory diseases and disorders)	2004	Granted	2025	Australia, Canada, China, Hong Kong, Israel, Japan, Mexico, Norway, Singapore, South Africa, Ukraine, Armenia, Austria, Azerbaijan, Belgium, Belarus, Switzerland, Germany, Denmark, Spain, France, United Kingdom, Ireland, Italy, Kyrgyzstan, Kazakhstan, Luxembourg, Moldova, Netherlands, Portugal, Russian Federation, Sweden, Tajikistan, Turkmenistan,
	Composition and Methods of Use	2004	Granted	2025	US, Armenia, Australia, Austria, Azerbaijan, Belarus, Brazil, Canada, China, Denmark, France, Germany, Hong Kong, India, Israel, Italy, Japan, Kazakhstan, Kyrgyzstan, Mexico, Moldova, Netherlands, Norway, Republic of Korea, Russian Federation, Singapore, South Africa, Spain, Switzerland, Tajikistan, Turkmenistan, and Ukraine
	Methods of Use (In combination with anti-IL-6/IL-6R antibodies)	2011	Pending	2032	US
	Formulations and dosing regimen	2016	Granted/Pending	2037	US Pending: Australia, Canada, China, Europe, Hong Kong, Israel, Japan, US
	Methods of Use (CNS disorders)	2017	Pending	2038	Canada, Europe, Japan, US
	Methods of Use (gastrointestinal/autoimmune/inflammatory)	2018	Pending	2039	PCT, Australia, Canada
	Composition and Methods of Use (CAR-T cell therapies)	2020	Pending	2041	US (Provisional)
	Method of use (coronavirus)	2020	Pending	2041	US (Provisional)
Milciclib (TZLS-201) *pan-CDK inhibitor*	Composition of matter, methods of use, process of manufacturing	2003	Granted/Pending	2024	US, Europe, Brazil, Eurasia, Africa, Algeria, Argentina, Australia, Barbados, Bosnia & Herzegovina, Canada, Colombia, Costa Rica, Croatia, Cuba, Ecuador, Georgia, Iceland, India, Indonesia, Israel, Japan, Korea, Kosovo, Malaysia, Mexico, Mongolia, Montenegro, New Zealand, Nicaragua, Norway, Pakistan, Philippines, Serbia, Singapore, South Africa, Sri Lanka, Taiwan, Trinidad & Tobago, Tunisia, Ukraine, Uzbekistan, Vietnam. Pending: US, Egypt, Thailand,, Venezuela
	Methods of use (multiple indications)	2008; 2009	Issued	2029; 2030	US, EU, China, Hong Kong, Japan
	Methods of use (combination therapies with cytotoxics)	2008; 2009	Issued/Pending	2029; 2030	US, EU, China, Hong Kong, Japan Pending: EU
	Compositions of related entities, formulations and methods of treatment	2009	Issued	2030	US, EU, China, Hong Kong, Japan
	Methods of use (combination therapies with therapeutic antibodies)	2006	Issued	2027	US, EU, China, Japan
	Formulations of Milciclib and therapeutic combinations of the same for use in the treatment of cancer	2017	Granted/Pending	2038	US, Pending: US, EU, Canada, Japan, Hong Kong
	Enteric-coated pharmaceutical formulations	2021	Pending	2042	US (Provisional)
TZLS-501 *fully human anti-IL6 receptor mAb*	Composition of Matter and Methods of use	2009	Issued/ Pending	2029	US, Austria, Australia, Belgium, Canada, China, Denmark, France, Germany, India, Ireland, Italy, Japan Luxembourg, Mexico, Netherland, Spain, Sweden, Switzerland and UK. Pending: US, Japan
	Composition of IL-6/IL-6R antibodies and methods of use (coronavirus includes combination with dactinomycin)	2020	Pending	2041	PCT, US

Executive Team

Management team has proven industry leadership and successful track record in independently bringing 3 drugs to market

Kunwar Shailubhai PhD, MBA
CEO & CSO
Executive Director

- Co-founder, EVP & CSO of Synergy Pharmaceuticals, NASDAQ: SGYP
- Inventor of antibody oral formulation technology and pioneer of GC-C agonist technology
- Inventor of TRULANCE® approved for Chronic constipation and IBS-C. Dolcantide successfully completed Phase 2 trial
- Prior experience at Callisto Pharmaceuticals and Monsanto

Neil Graham MBBS, MD, MPH
CMO

- Expert in Medicines development and Infectious Diseases Epidemiologist
- Global Development Expertise in Clinical Development and in Medical Affairs
- Prior experience at Regeneron, Vertex, Trimeris Inc, XTL Biopharmaceuticals, Glaxo Welcome.

Tom Adams PhD
Executive Director

- Over 35 years experience in pharma/biotech/medical companies
- Led the development of onvansertib, for treatment of KRAS-mutated metastatic colorectal cancer (mCRC)
- Prior Experience at Cardiff Oncology, Hepion Pharmaceuticals, Clearbrige Biophotonics and Synergy.

Gabriele Cerrone, MBA
Executive Chairman

- Founder and chairman of two biotech companies with market cap over $2B
- Inhibitex sale for $2.5B
- Prior experience at Synergy, Trovagene, Gensignia, Rasna, Contravir, and Siga Technologies
- MBA, Stern School of Business, NY, US.

Willy Simon
Non-Executive Director

- Career as an executive in the banking and corporate finance sector and director of publicly listed companies
- Kredietbank N.V., Citibank, Generale Bank NL, CEO of Fortis Investment Management
- Chairman of Bank Oyens & van Eeghen, Partner at Redi & Partners

John Brancaccio
Non-Executive Director

- Over 35 years financial experience in pharma/biotech/medical devices with over 15 years experience with multiple public companies
- Management and SEC reporting
- Private and public fundraising experience

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Scientific Advisory Committee

Howard Weiner, MD

- Professor of Neurology at Harvard Med
- Director and Founder of the Partners MS Center and Co-Director of the Ann Romney Center for Neurologic Diseases
- Pioneered investigation of the mucosal immune system for the treatment of autoimmune and other diseases

Kevin Herold, MD

- Professor of Immunobiology and Medicine and Deputy Director, Yale Center for Clinical Investigation
- Director of the Yale Diabetes Center and Director of the TrialNet Center at Yale
- Expert in autoimmune diseases and anti-CD3 monoclonal antibody therapies

Arun Sanyal MD

- Charles Caravati Distinguished Professor and Chair, Division of Gastroenterology, Hepatology and Nutrition at Virginia Commonwealth University School of Medicine
- Leader in the field of liver diseases

Napoleone Ferrara MD

- Inventor of Avastin® ($6.67Bn/yr)*; 2010 Lasker Award
- Senior Deputy Director Basic Sciences, Moores Cancer Center, UC San Diego
- Distinguished Prof of Pathology, School of Medicine, UC San Diego

Angelo Sangiovanni, MD

- Adjunct Professor of Gastroenterology at the University of Milan
- Leader in liver disease and gastroenterology
- Awarded Best Scientific Publication in clinical Hepatology in Italy

Fabio Piscaglia, MD

- Associate Professor, Medical and Surgical Sciences at the University of Bologna
- Leader in liver diseases and transplantation
- 2017 Winner of a National Institute of Health (NIH) of United States of America grant

Erica Villa, MD

- Professor and Chief GI Unit
- Chairman of the Department of Internal Medicine
- Universitaria di Modena, Policlinico, Modena, Italy
- Leader in Clinical Hepatology and Translational Medicine

Capital Structure

	TILS Ordinary Shares	TLSA ADS
• Issued share capital	194,612,289	97,306,144
• Warrants (WAEP: £1.86)	1,183,491	591,746
• Options (WAEP: £0.68)	21,773,678	10,886,839
Fully Diluted Shares	**217,569,458**	**108,784,729**

*Information prepared as of 29 April 2021. 1 ADS represents 2 ordinary shares.

CONTACT US

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