
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
UNDER THE SECURITIES EXCHANGE ACT OF 1934

October 2022

Commission File Number: 001-38723

Tiziana Life Sciences LTD
(Exact Name of Registrant as Specified in Its Charter)

9th Floor
107 Cheapside
London
EC2V 6DN
(Address of registrant's principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of 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):

INFORMATION CONTAINED IN THIS REPORT ON FORM 6-K

On October 25, 2022, Tiziana Life Sciences LTD (the “Company”) issued this 6K announcing the release of an updated corporate deck, that can also be found on the Tiziana Life Sciences LTD website.

The Announcement is furnished herewith as Exhibit 99.1 to this Report on Form 6-K. The information in the attached Exhibit 99.1 is being furnished and shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, or otherwise subject to the liabilities of that Section, nor shall it be deemed incorporated by reference in any filing made by the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, except as otherwise set forth herein or as shall be expressly set forth by specific reference in such a filing.

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.

TIZIANA LIFE SCIENCES LTD

Date: October 25, 2022

By: /s/ Keeren Shah
Name: Keeren Shah
Title: Finance Director

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Corporate deck, dated October 25, 2022



***Enabling Breakthrough Immunomodulation
Approaches to Enhance the Functionality of
Treg-Based Therapies***

NASDAQ: TLSA



Disclaimer and Forward-Looking Statement

The content of this presentation has been prepared for the purpose of providing general information about, and an overview of, the Company and its business. It is not intended to be a complete review of all matters concerning the Company and nor has it been independently verified. Whilst the presentation has been prepared in good faith and the Company has taken all reasonable care to ensure the information and facts contained in this presentation are accurate and up-to-date, it does not make any representation or warranty, express or implied, as to the accuracy or completeness of any information included in this presentation. Neither the Company nor any of its directors, officers, employees or agents shall be liable for any loss arising directly or indirectly from the use of or reliance upon this presentation or in relation to the adequacy, accuracy, completeness or reasonableness of the information it contains. All and any such liability is expressly excluded to the fullest extent permitted by law. The information in this presentation is subject to updating, completion, revision, further verification and amendment without notice.

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This presentation may contain certain forward-looking statements concerning the financial condition, results of operations and businesses of the Company. All statements other than statements of historical fact are, or may be deemed to be, forward-looking statements. Forward-looking statements are statements of future expectations that are based on management's current expectations and assumptions and involve known and unknown risks and uncertainties that could cause actual results, performance or events to differ materially from those expressed or implied in these statements. All forward-looking statements contained in this presentation are expressly qualified in their entirety by the cautionary statements contained or referred to in this section. You should not place undue reliance on forward-looking statements. Each forward-looking statement speaks only as of the date of this presentation. The Company does not undertake any obligation to publicly update or revise any forward-looking statement as a result of new information, future events or other information. In light of these risks, results could differ materially from those stated, implied or inferred from the forward-looking statements contained in this presentation.

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Investment Highlights



Innovative, clinically-validated, drug delivery platform based on immunomodulating approaches
Recent clinical data support the MOA



Global IP protection of antibody formulation technology until 2040, can be applied across different molecules
Strong IP protection for lead assets
Miliclib and Foralumab



Partnership with Precision Biosciences for lymphodepletion ahead of CAR-T procedures.
Collaboration ongoing



Targeting the global \$150+ billion market for antibody treatments¹
Clinical data validate MOA for nasal administration



Experienced scientific advisory board and management team that has brought four drugs to market
Demonstrated Bench to market experience

A Revolutionary Platform

Antibody Administration: Switching From IV and SC To Oral, Nasal And Inhaled Routes for Immunomodulating Therapies

Today's Options for Antibody Administration are Subcutaneous or Intravenous (IV)



tiziana
The platform enables...



Foralumab
Oral administration
For Crohn's Disease
IBD



Foralumab
Nasal administration
Multiple Sclerosis
Neurodegenerative diseases



TZLS- 501 Anti- IL6R
Direct delivery to lungs
with a portable inhaler
for pulmonary diseases

Benefits of non-systemic dosing

- Improved patient compliance
- Local activity instead of systemic distribution; may minimize side effects
- Anticipated lower cost of goods and lower price of administration

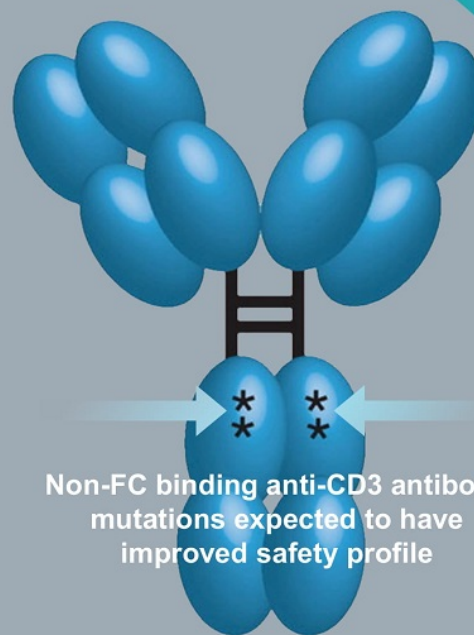
Our Pipeline

Positive Data From Five Clinical Studies Completed

	Subject	PC	IND	Phase 1/IAP	Phase 2	Phase 3
FORALUMAB <i>Fully human anti-CD3 mAb</i>	Intranasal	Progressive Multiple Sclerosis (expanded program)			Ongoing IAP, 6 months data showed positive clinical response	
	Oral	Crohn's Disease				
	Subcutaneous	Type 1 Diabetes				
ANTI IL-6 RECEPTOR <i>Fully human mAb</i>	Inhalation	Pulmonary Fibrosis				
MILCICLIB <i>Pan-CDK inhibitor</i>	Oral	Milciclib + Gemcitabine in NSCLC Kras+ mutants				

Lead Asset: Foralumab

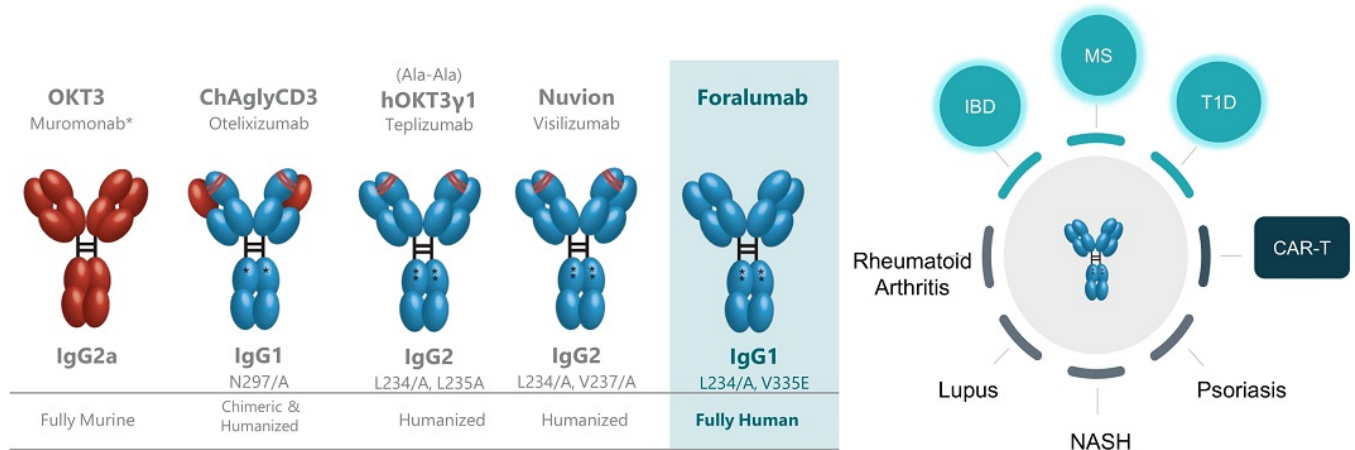
The only **fully human** anti-CD3
monoclonal antibody in clinical studies



Non-Fc binding anti-CD3 antibody
mutations expected to have
improved safety profile

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

CD3-specific Monoclonal Antibodies in Clinical Development

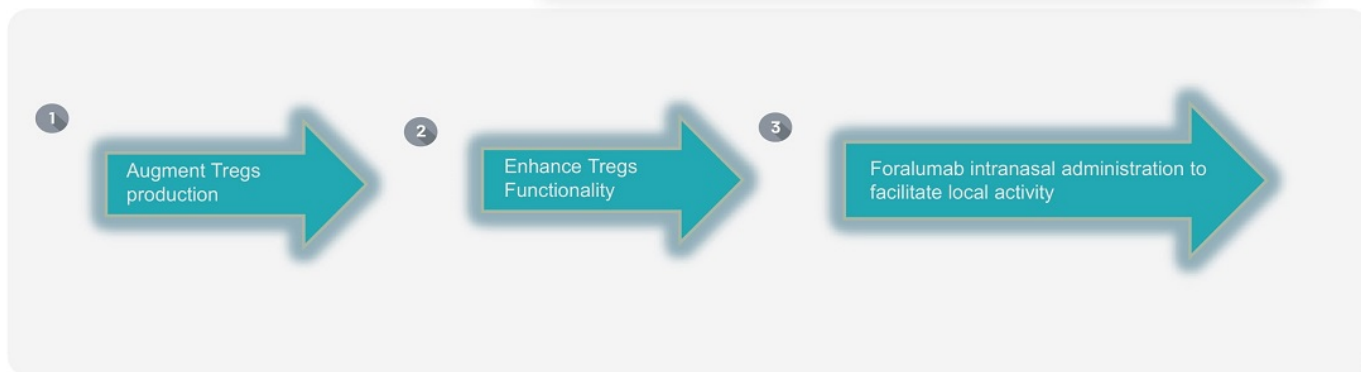


Adapted from: Kuhn, Chantal, and Howard L. Weiner. "Therapeutic anti-CD3 monoclonal antibodies: from bench to bedside." *Immunotherapy* 8.8 (2016): 889-906.

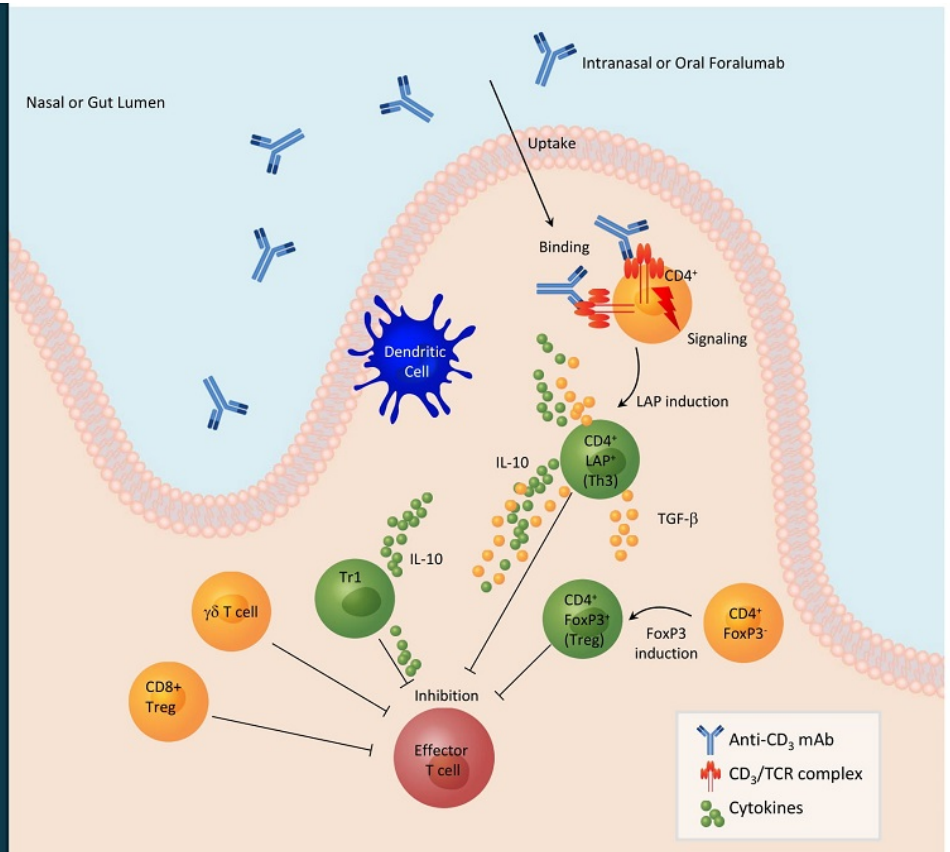
Foralumab Facilitates Locally Targeted Immunomodulation to Improve Tregs Production and Enhance their Functionality

Our Therapeutic Approach

Site targeted local immunomodulation

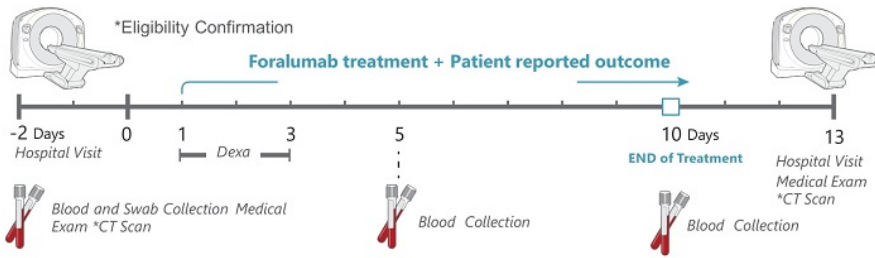


The binding of foralumab to the T-cell receptor complex, through either the nasal or oral route, results in suppression of effector T-cells involved in various inflammatory and autoimmune diseases along with a reduction in inflammatory cytokines and increase in Tregs anti-inflammatory cytokines.

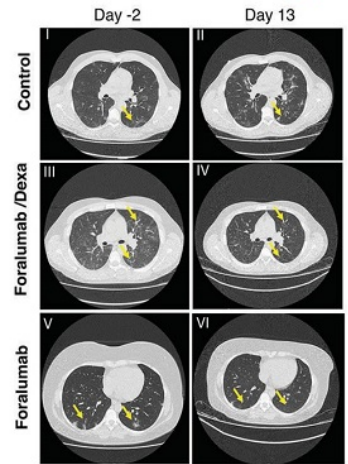


Foralumab: Clinical Proof of Concept for Intranasal Delivery First Demonstrated in Mild-to-Moderate COVID-19

The First Validation That Intranasally Administered Foralumab is Well-tolerated and the Treatment Provides Clinical Benefits



CT Scan of Patients' Lungs



Results: Biomarkers measured via cytokines and C-reactive proteins

Cohort	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

Precision Biosciences (Nasdaq: DTIL) Licensing Collaboration Validates Our Technology

First foralumab Program to be Tested Will be in Combination with an Anti-CD19 CAR-T

- Exclusive agreement allowing Precision to explore Tiziana's fully human anti-CD3 monoclonal antibody (mAb), foralumab, as an agent to induce tolerance of allogeneic CAR-T cells to potentially improve the clinical outcome of Precision's CAR-T cell therapy programs
- Foralumab to be used as a potential mild pre-conditioning and lymphodepleting agent to replace or reduce doses of cyclophosphamide/fludarabine (Cy/Flu)

Upfront payments

- Multiple payments commensurate with meeting specified successful milestones
- Royalties
- Additional royalty options for subsequently developed CAR-T products
- Precision to be responsible for the development, commercialization and costs for use of foralumab

**Intranasal Foralumab for
Treatment of Neurodegenerative
Diseases (Multiple Sclerosis)**

Local action with improved
safety and lowered dosing

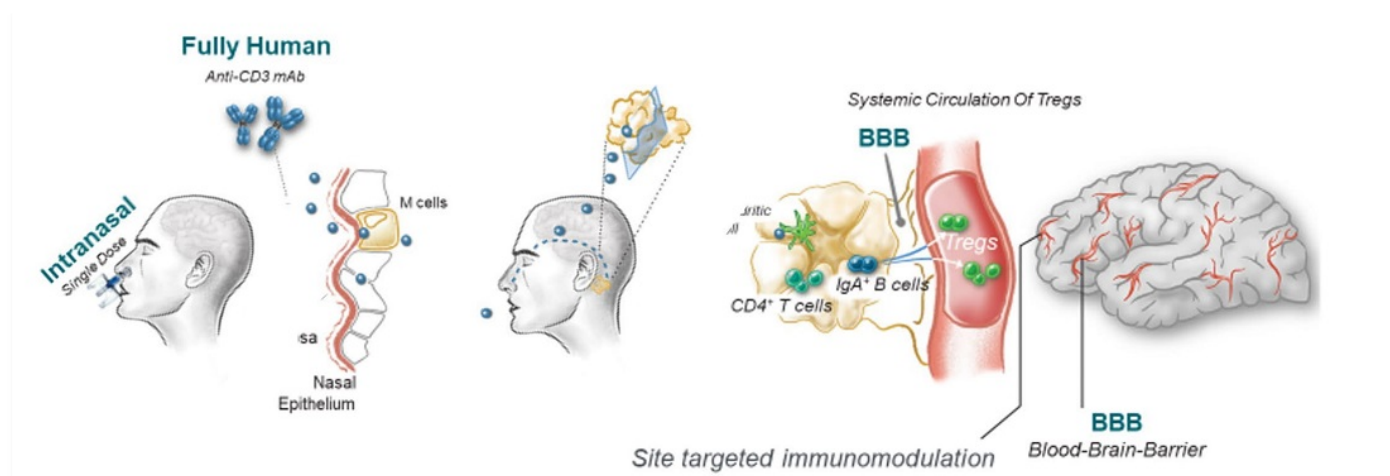
**Fully Human
Anti-CD3 mAb**

Intranasal



Intranasally-Administered Foralumab for Neurodegenerative Diseases

An Innovative Approach to Penetrate the Blood Brain Barrier (BBB)



Intranasally Administered Foralumab in SPMS Patient: 6-Month Treatment Data

Two patients were dosed with intranasal foralumab M-W-F for two weeks with a subsequent 1-week washout period for 6-month period. Data consistent with 3-month period.

Positive Results: The regimen was well-tolerated with associated beneficial clinical and biomarker changes

Clinical Results

PET imaging data

- Indicated continued inhibition of microglial cell activation
- The reduction in microglial activation was seen in all parts of brain
- Suppression of microglial activation further increased after six months of treatment

Clinical Test Evaluation

- Improvement in Timed 25-Foot Walk Test (T25FW)
- 9-Hole Peg Test (9HPT)
- Symbol Digit Modality Test (SDMT)

Biologic Response

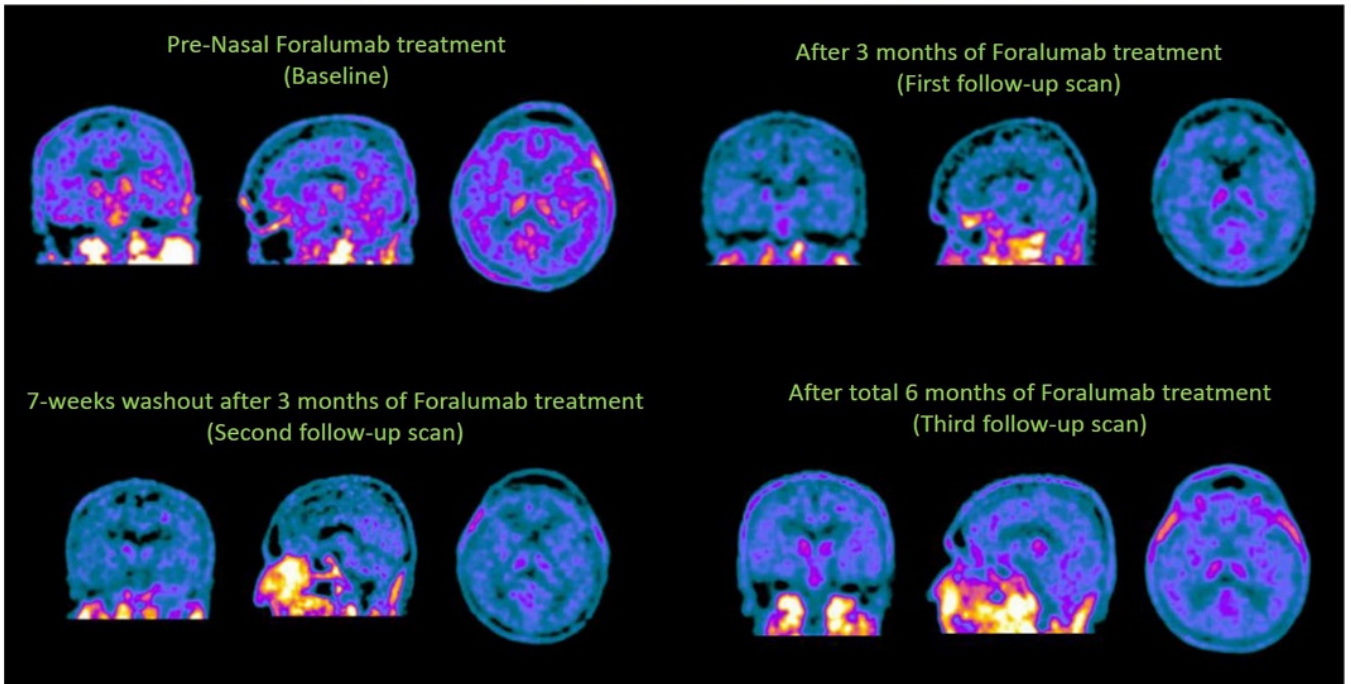
Biomarker changes

Downregulated serum levels of pro-inflammatory cytokines*, including:

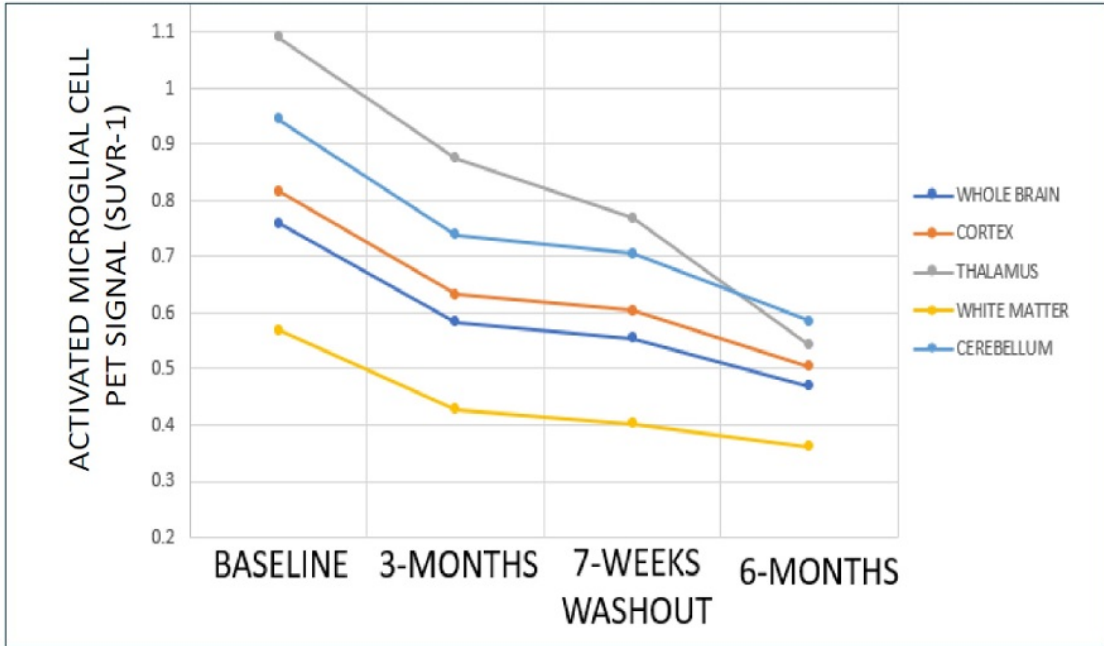
- Interferon-gamma (IFN-g)
- Interleukin (IL)-18
- IL-1b
- IL-6

*These biomarkers are known to be associated with multiple sclerosis pathogenesis and progression

Assessment of Inhibition of Microglial Activation by PET Imaging Following Treatment with Nasally Administered Foralumab in First SPMS Patient



Graph Depicting Microglial Activation PET Signal in Different Regions of the Brain at Various Time Points



Intranasally Administered Foralumab in SPMS Patient: 6-Month Treatment Data

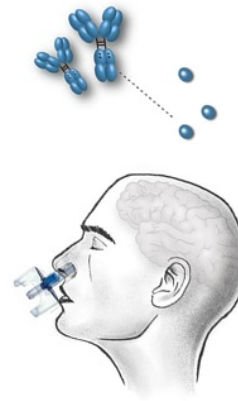
Percent Reduction* in Microglial PET Signal After Starting Intranasal Foralumab as Compared to Baseline, in Whole Brain and Selected Brain Regions

	WHOLE BRAIN	CEREBRAL CORTEX	THALAMUS	WHITE MATTER	CEREBELLUM
3 months	-23%	-23%	-20%	-25%	-22%
6 months	-38%	-38%	-50%	-36%	-38%

*Percent reduction is based on changes from baseline in SUVR-1, a surrogate index for PET binding potential. SUVR=Standardized Uptake Value Ratio, calculated with reference to a pseudo reference region in cerebral white matter that showed minimal change in PET SUV, across time points.

The clinical data from the second patient is consistent with clinical data from the first patient. These results confirm that intranasally administered foralumab produces positive clinical responses

**Other Potential CNS-related
Indications
(Alzheimer's and ALS)**



Intranasal anti-CD3 provides a unique approach for treating progressive neurologic diseases by modulating microglial cells. The intranasal route of immunotherapy has minimal toxicity and induces regulatory T cells locally, that then migrate to the brain to dampen brain inflammation.

Proof-of-Concept Demonstrated in Alzheimer's Disease

Study Presented at the Alzheimer's Association International Conference® (AAIC®)

“Treatment of Alzheimer's disease by modulation of microglial neuroinflammation by nasal anti-CD3 mAb” (presented by Weiner, M.D., Co-Director of the Ann Romney Center for Neurologic Disease at the Brigham and Women's Hospital (BWH) and Chairman of Tiziana's Scientific Advisory Board)

In this study animal models of Alzheimer's disease (AD) demonstrated that microglia activity was restored and cognition was improved following the dosing of intranasal anti-CD3 monoclonal antibody.

- Clinical measures were assessed in the mouse models using the Y-maze and Morris water maze tests which showed improvements in cognition. Biological improvements were also observed based on restoration of genetic phenotypes as measured by the presence of homeostatic microglia genes detected by Nanostring. In addition, it was found that intranasal anti-CD3 induced the migration of regulatory T cells (Tregs) to the brain which then interacted with microglia.
- Alzheimer's is another potentially valuable application of anti-CD3 based on its ability to stimulate the immune system to promote homeostatic microglial cells while decreasing degenerative microglial cells in the brain.

IND for Intranasal Foralumab in Alzheimer's Planned Submission Q2/Q3 2023

Receive an affirmative written response from the FDA on a Pre-Investigational New Drug Application (PIND)

Submit an Investigational New Drug Application (IND) to conduct a Phase 1 study intranasal foralumab in Alzheimer's disease patients

Planned IND filing by Q3 2023 upon the completion of requested toxicology studies

Start Phase 1 program in 2H of 2023

Intranasal Foralumab in Amyotrophic Lateral Sclerosis (ALS)

◆ ALS patients have limited therapeutic options and high unmet need ◆

- In September, a Lawrence & Isabel Barnett Drug Development Program Grant was awarded to the Ann Romney Center for Neurologic Diseases at Brigham and Women's Hospital (BWH) by the ALS Association
- This prestigious research grant supports the study of an intranasal anti-CD3 monoclonal antibody (mAb) in an animal model of Amyotrophic Lateral Sclerosis (ALS).
- The grant will allow further study the role of intranasal anti-CD3 mAb in dampening the microglial activation which amplifies ALS disease progression.

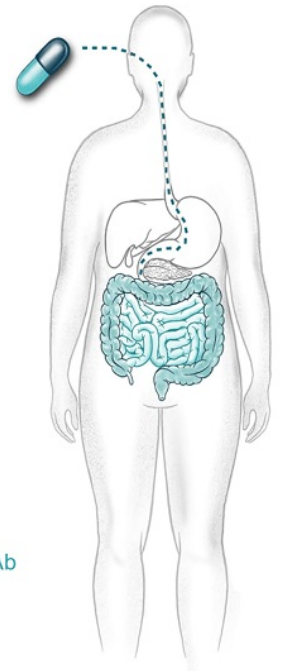
“We have now seen the potential of intranasal foralumab to dampen microglial activation in three major neuroinflammatory-related diseases, which creates significant optionality for exploring its benefits in some of the most important and burdensome medical conditions of our time.”

Oral Foralumab for
Inflammatory Bowel
Diseases
(Crohn's Disease)

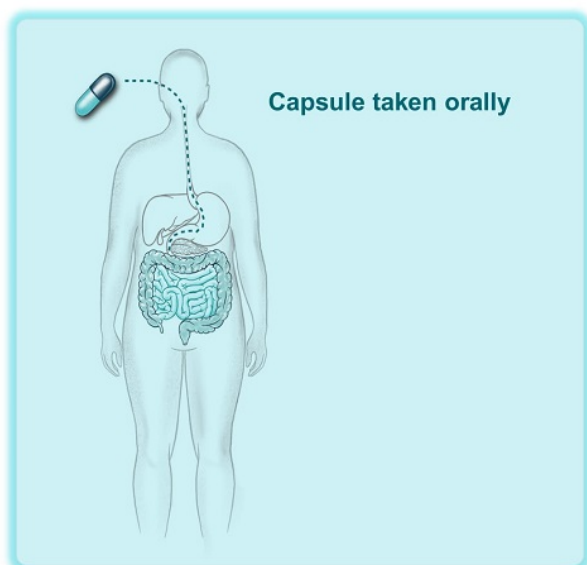


Oral capsules

Foralumab, a fully human anti-CD3 mAb



Orally-Administered Foralumab in Phase 1a Trial in Healthy Volunteers



Clinical results

Single ascending dose, double-blind, placebo-controlled study in healthy subjects

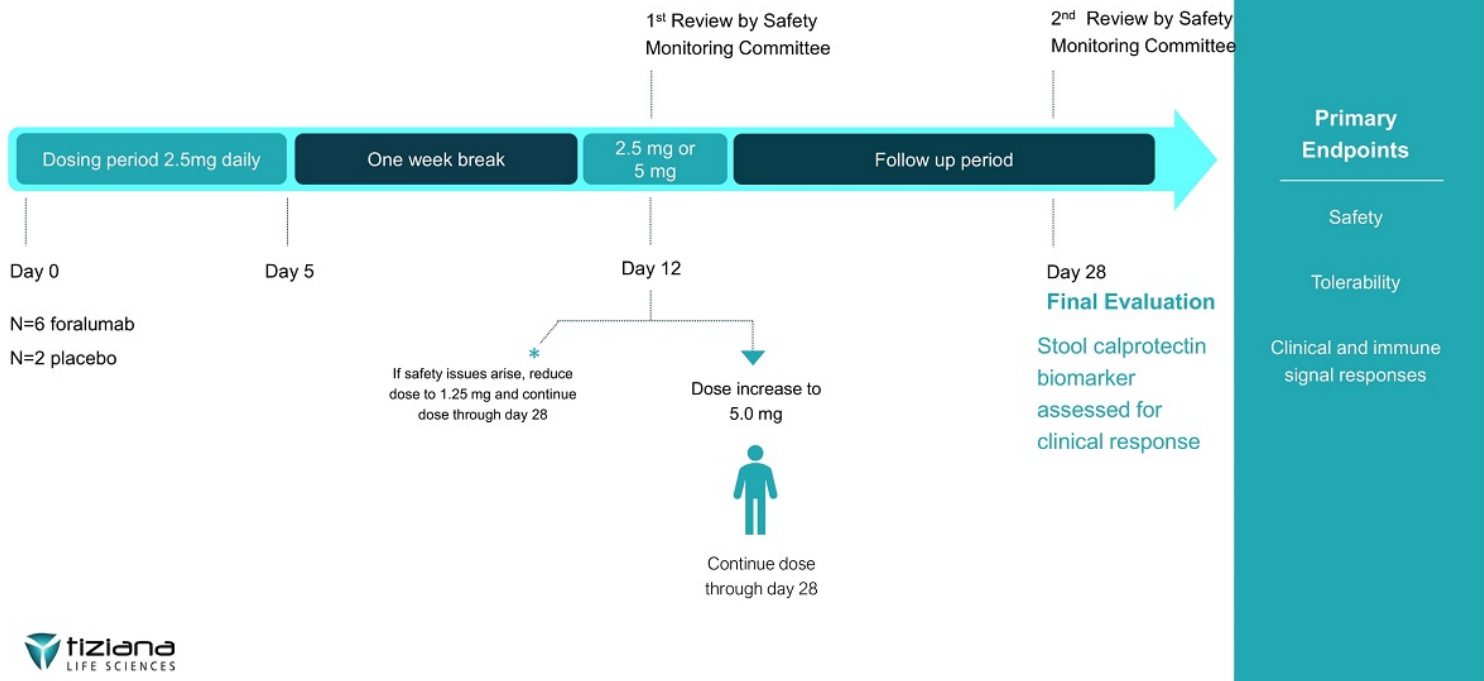
Foralumab administered at 1.25, 2.5 and 5.0 mg/dose in enteric-coated capsules

Well-tolerated at all doses tested and no drug-related safety issues observed

No systemic absorption of orally administered foralumab

Phase 1B Study Design in Crohn's Disease

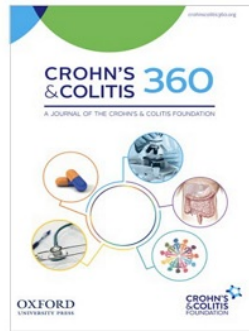
Oral Foralumab Dosing (n=8)



Validated Proof of Concept for Oral Administration of OKT3, an Anti-CD3 mAb in Ulcerative Colitis

Key Findings

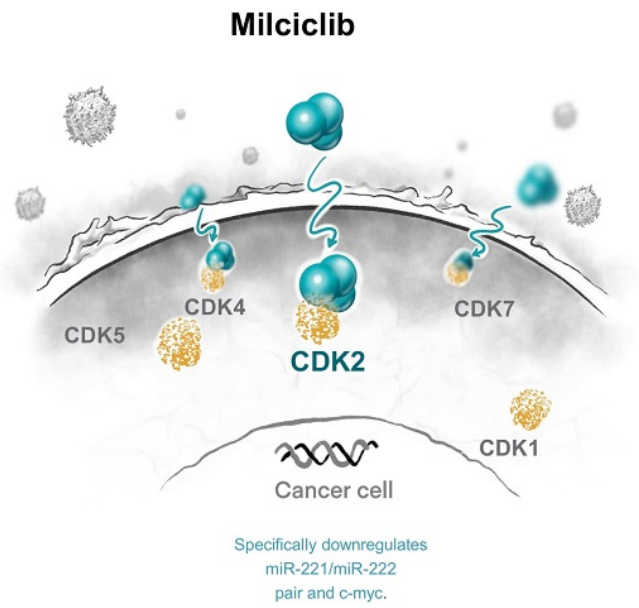
- ✓ OKT3 was approved for renal transplantation patients but is now off the market due to toxicity concerns
- ✓ Prof. Snapper, et al., of Harvard Medical School conducted an exploratory study with oral OKT3 treatment in patients with ulcerative colitis, an inflammatory bowel disease
- ✓



- Biologic response of increased proliferation and anti-inflammatory gene expression profile in peripheral blood mononuclear cells
- 3 of 6 patients had a clinical response including one patient in clinical remission
- Treatment was well-tolerated with no serious treatment-related adverse events
- Patients with moderate-to-severe ulcerative colitis received oral OKT3, a fully-murine anti-CD3 mAb once daily for 30 days

Oral Milciclib for NSCLC

Broad-spectrum inhibitory activities of milciclib on CDKs are favorable



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)

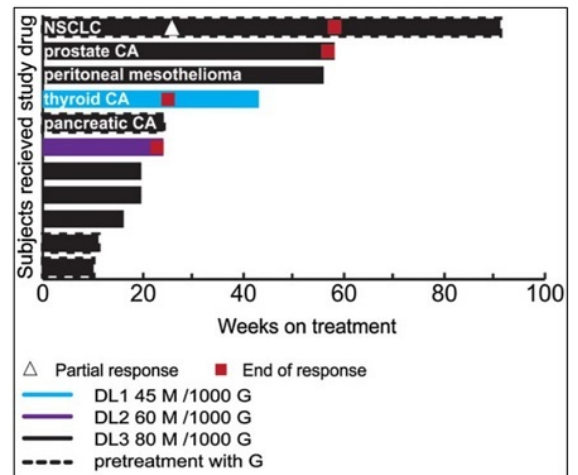
Results

Milciclib was well-tolerated with manageable side effects

Overall response rate was 36%

Clinical activity was observed in patients with variety of solid cancers who were non-responders to all existing chemotherapy

Recommended Phase 2 dose (RPD) found to be 80mg/m²/day



Swimmer plot 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

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