



TLSA: NASDAQ TILS: **AIM**



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LIFE SCIENCES

An Innovative Platform in Oral and
Nasal Antibody Administration

A Novel Approach for Treatment
of Hepatocellular Carcinoma

February 2020

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We have filed a registration statement (including a preliminary prospectus supplement) with the SEC for the offering to which this presentation relates. Before you invest, you should read the preliminary prospectus supplement and the accompanying prospectus (including the risk factors described therein) and other documents we have filed with the SEC for more complete information about us and the offering.

You may access these documents for free by visiting EDGAR on the SEC web site at <http://www.sec.gov>. Alternatively, copies of the preliminary prospectus supplement and the accompanying prospectus relating to the securities being offered may be obtained from ThinkEquity, a division of Fordham Financial Management, Inc., 17 State Street, 22nd Floor, New York, New York 10004, by telephone at (877) 436-3673, or by email at prospectus@think-equity.com. The preliminary prospectus supplement dated February 14, 2020 is available on the SEC web site at <http://www.sec.gov>.

EXECUTIVE TEAM



**Kunwar Shailubhai PhD,
MBA
CEO & CSO
Executive Director**

- Co-founder , EVP & CSO of Synergy Pharmaceuticals, NASDAQ: SGYP
- The pioneer of GC-C agonist technology
- Inventor of TRULANCE® approved for Chronic constipation and IBS-C
- VP, Callisto Pharmaceuticals
- Group Leader, Monsanto Co.



**Tiziano Lazzaretti
Chief Financial Officer**

- Previously Group Finance Director at Pharmentis –Teva Ratiopharm spin off
- Executive Director at Alliance Boots, Snia, Accenture and FIAT Group
- MBA, Bocconi University, Milan
- Corporate Finance, London Business School. BSc Accounting and Finance

Key Strengths of the Management Team

- Successful record in biotechnology 'Bench to Market'
- Proven credentials in Science and Business
- Strong history in entrepreneurship and Biotechnology deals
- Decades of experience in Pharma Industry

BOARD OF DIRECTORS



**Gabriele Cerrone, MBA
Executive Chairman**

- Proven track record & experience in financing biotechnology companies
- Founder and chairman of two biotech companies with market cap over \$2 B
- Inhibitex sale \$2.5 B
- Synergy / Trovagene / Gensignia / Rasna / Contravir / 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



**Gregor MacRae
Non-Executive Director**

- Business adviser and specialist in taxation and cross border solutions.
- Senior Partner of Appledore Wealth Management LLP, a London-based high net worth business advisory partnership.
- Former Director of an international trust Co.
- LLB (Hons) University of Birmingham and qualified Chartered Accountant (ICAEW)

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
-

INVESTMENT HIGHLIGHTS

- **Transformational platform technologies:** Proprietary oral and nasal formulation technologies to transform *immunotherapies with Monoclonal Antibodies ('mAbs')* currently administered intravenously
- **Oral immunotherapy for Crohn's Disease (CD):** Phase 2 clinical study with orally administered Foralumab, a fully human anti-CD3 mAb: *Anticipated completion date Q4, 2020*
- **Nasal treatment for progressive multiple sclerosis (pro-MS):** Phase 2 clinical study with nasally administered Foralumab: *Anticipated completion date Q1, 2021.*
- **Innovative Approach:** Nasally administered Foralumab upregulates T regulatory cells (Tregs) that are capable of crossing '*Blood Brain Barrier*' to suppress inflammation in brain commonly associated with Neurodegenerative diseases such as, *Multiple Sclerosis, Alzheimer and Lupus (systemic lupus erythematosus)*
- **Broad-spectrum treatment for hepatocellular carcinoma (HCC):** Milciclib, a pan-CDK (cyclin dependent kinase) inhibitor, successfully completed phase 2 clinical trial in advanced HCC patients
- **Orphan Drug Designation for Milciclib: Granted in US and EU for treatment of thymic carcinoma/thymoma (TC/T)**
- **Strong intellectual property**
 - ✓ 255 patents approved and 30 pending
 - ✓ Covers composition of matter, manufacturing process and disease indications
 - ✓ Oral formulation technology applicable to other mAbs therapeutics

Foralumab
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Nasal Trial: Phase 2 starting shortly

Phase 1 trial completed

Phase 2 data in pro-MS by Q1, 2021

Oral Trial: FDA approved IND

Phase 1 oral trial completed

Phase 2 oral in CD by Q4, 2020

Milciclib
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Orphan Drug Designation: Met primary and secondary endpoints in 2 separate Phase 2 trials in TC/T

Phase 2a in sorafenib-resistant HCC patients completed

Milciclib seems to outperform Standard of care

A REVOLUTIONARY PLATFORM

SWITCH ANTIBODY ADMINISTRATION FROM INTRAVENOUS TO ORAL AND NASAL ROUTES

TODAY'S ANTIBODY ADMINISTRATION OPTIONS ARE MOSTLY I.V.



- Costly Infusion
- Poor patient compliance
- Higher toxicity
- Systemic treatment to affect whole body
- Infusion related side effects

tiziana
platform enables...



Antibodies (mAbs)
reformulated for oral
administration



Antibodies (mAbs)
reformulated for nasal
administration

THE CHOICE OF ORAL OR NASAL ADMINISTRATION ROUTES WILL DEPEND ON THERAPEUTIC INDICATION

PATIENT & PROVIDER BENEFITS

Ease of use
Superior compliance
Topical action in gut
Minimized toxicity
Take home Rx
No costly infusion

THE LARGE MARKET OPPORTUNITY

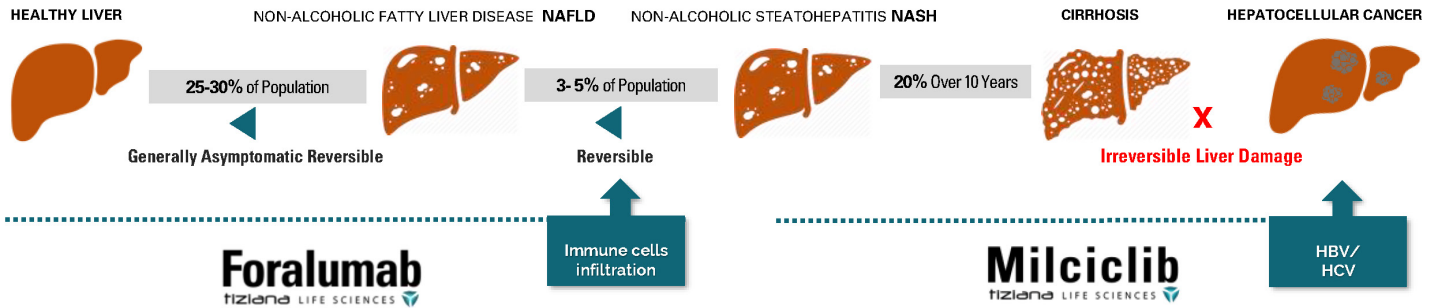
Market opportunity for mAb therapeutics is greater than

**\$86
BILLION**

THE MULTI BILLION DOLLAR MARKET FOR CROHN'S DISEASE AND NASH

EXCESSIVE FAT DEPOSITS LEAD TO LIVER INFLAMMATION

INFLAMMATORY AND FIBROTIC PROCESSES LEAD TO MALIGNANCY



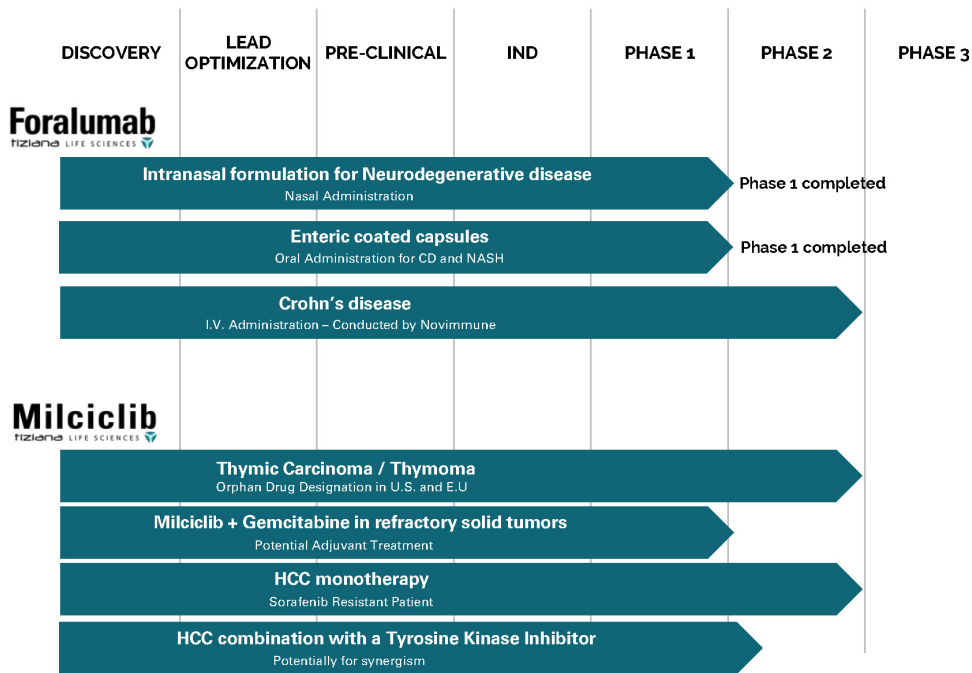
Foralumab (Anti-CD3) for NASH and Crohn's Disease

- NASH global market ~ \$35 B/year
- Crohn's Disease market: \$10B /year by 2025
- Oral/nasal delivery is a novel, completely differentiated approach
- Strong IP on the 'Revolutionary' approach with significant market potential

Milciclib for Liver Cancer

- HCC (\$1.5B /year by 2022): Medical need for a safer and effective drug with higher responder rates
- Milciclib: An oral drug with completely differentiated MOA and long-term safety
- Superior safety profile

DEVELOPMENT PIPELINE



Foralumab
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PHASE 2 TO BEGIN
Nasal Trial
Pro-MS

Foralumab
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PHASE 2 TO BEGIN
Oral trial in
Crohn's Disease

Milciclib
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TWO PHASE 2 TRIALS COMPLETED
TC / T Oral

Milciclib
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PHASE 2a COMPLETED
HCC Oral
Monotherapy



**A BIOTECHNOLOGY PLATFORM ENABLING
ORAL AND NASAL
ADMINISTRATION OF FORALUMAB AND
OTHER MONOCLONAL ANTIBODIES**



NASAL ADMINISTRATION

Phase 1 trial completed for related neurodegenerative diseases such as Progressive Multiple Sclerosis (Pro-MS) .

Phase 2 trial in Pro-MS to start shortly. This novel approach has potential for treatment of Alzheimer and lupus diseases as well



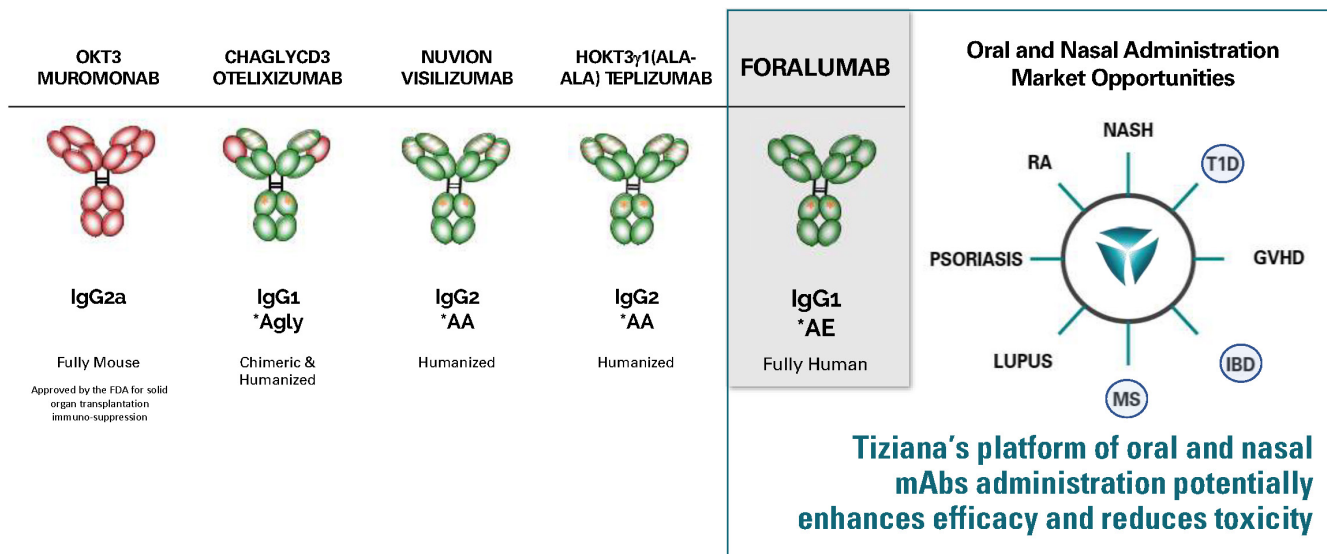
ORAL ADMINISTRATION

Successfully completed Phase 1 trial with orally administered Foralumab

Phase 2 trial in Crohn's Disease to start shortly

THE ONLY FULLY HUMAN ANTI-CD3 MAB IN CLINICAL TRIALS

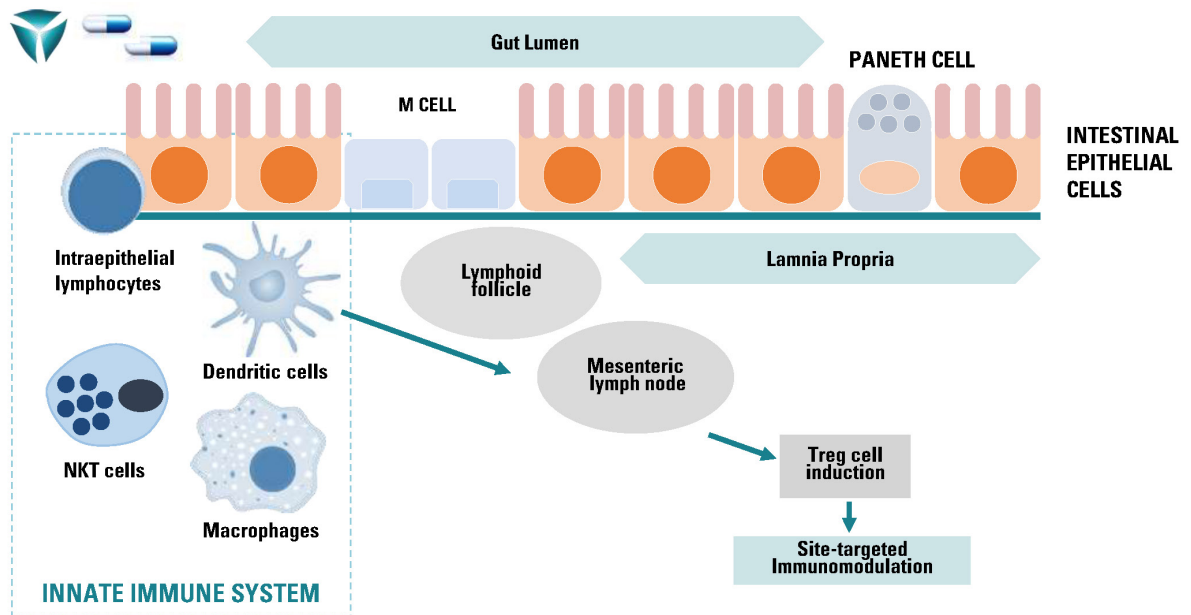
CD3-SPECIFIC MONOCLONAL ANTIBODIES IN CLINICAL DEVELOPMENT



Foralumab is unique: functionally equivalent to OKT3 with minimal immune reactions when administered IV

HOW DOES OUR PLATFORM TECHNOLOGY WORK?

NOVEL APPROACH FOR SITE-TARGETED IMMUNOMODULATION



ORAL AND NASAL FORMULATION PATENTS PENDING

Nasal administration of **Foralumab**

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- ✓ Proof-of-concept demonstrated in animal studies
- ✓ Phase 1 study for neurodegenerative diseases at Brigham and Women's Hospital, Harvard Medical School; completed and well-tolerated up to 250 µg
- ✓ Positive Top line data received August 2019, CSR in preparation
- ✓ In-licensed nasal delivery technology from Brigham and Women's Hospital, Harvard Medical School
- ✓ **Targets: Pro-MS and Alzheimer**

Patent covers **Foralumab** and other mAbs

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ANTI-CD3 ANTIBODY FORMULATIONS

Applicant(s): Tiziana Life Sciences PLC

Inventor(s): SHAILUBHAI, Kunwar

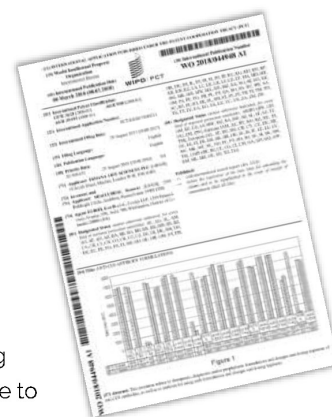
US Non-Provisional Patent Application
No.:62/380,652, filed August 29, 2016

PCT Application
PCT/US2017/049211, filed, Aug 29, 2017

Patent estate

- Exclusive license for composition of matter
- Composition of matter patent for oral formulation
- Additional patent applications pending
- Oral formulation technology applicable to other mAbs

Targets: Crohn's Disease and NASH



PHASE 1 CLINICAL DATA WITH NASALLY ADMINISTERED FORALUMAB

- Phase 1 Trial Conducted at Brigham and Women's Hospital Completed July 2019
- Dose-ranging, double-blind, placebo-controlled study in healthy subjects
- Foralumab was administered nasally at 10, 50 and 250 µg per day, consecutively for 5 days using a hand-held spray device
- Each dose group consisted of 6 active and 3 placebo

KEY FINDINGS

- Foralumab was well-tolerated with no drug-related toxicities
- Immunology marker analysis indicated, that 50-µg dose **stimulated the anti-inflammatory cytokine IL-10 and suppressed the pro-inflammatory cytokine IFN-γ**
- Results suggest **stimulation of T regs** needed for clinical benefits



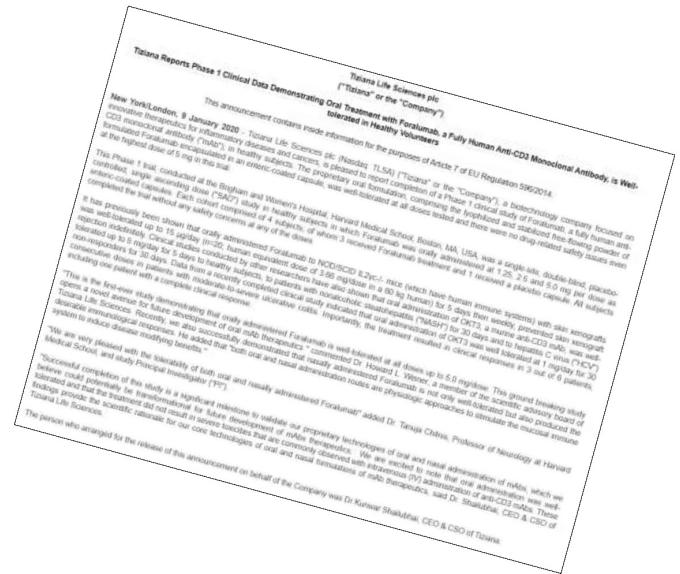
Press Release Reference: <https://ir.tizianalifesciences.com/news-releases/news-release-details/tiziana-life-sci-plc-phase-1-clinical-data>

PHASE 1 CLINICAL DATA WITH ORALLY ADMINISTERED FORALUMAB

- 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
- No apparent toxicity up to 5 mg

KEY FINDINGS

- Well-tolerated at all doses tested
- No drug-related safety issues observed
- Toxicities associated with IV administration of anti-CD3 mAbs not observed



Press Release Reference: <https://ir.tizionalifesciences.com/news-releases/news-release-details/tizona-life-sci-plc-further-re-foralumab-phase-1-trial>

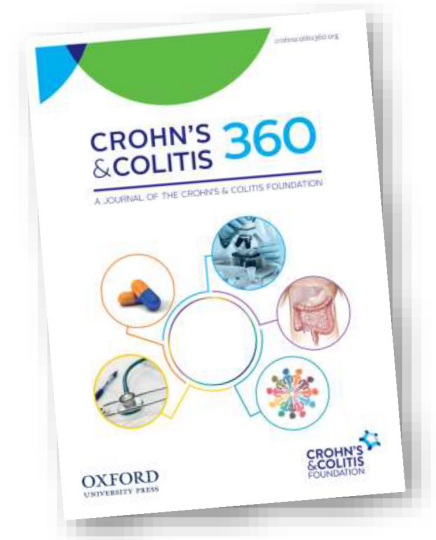
THE CONCEPT FOR ORAL ADMINISTRATION WITH ANTI-CD3 MAB IS VALIDATED WITH CLINICAL DATA IN ULCERATIVE COLITIS

- Determined the immunologic effects and safety of orally delivered anti-CD3 antibody in patients with moderate-to-severe ulcerative colitis (UC)
- Six subjects received oral OKT3

KEY FINDINGS

1. The biologic **response to treatment with oral anti-CD3 were 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.



PROOF-OF-CONCEPT IN NASH PATIENTS

ORAL TREATMENT WITH MURINE ANTI-CD3 (OKT3) EFFECTIVE IN A PHASE 2 TRIAL WITH NASH¹

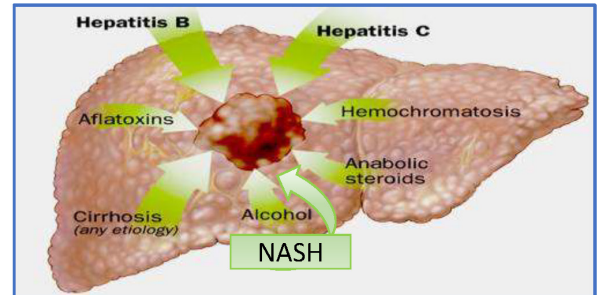
STUDY DESIGN	SAFETY	IMMUNOLOGICAL	EFFICACY BIOMARKERS
<ul style="list-style-type: none"> ▪ 36 subjects with NASH and type II diabetes ▪ Randomized, single-blinded, placebo-controlled ▪ 9 per group, not powered for statistical significance ▪ 0.2, 1.0, 5.0 mg or placebo daily for 30 days ▪ Primary endpoints: safety and trends in immunomodulation ▪ Secondary endpoint: indication or trend of efficacy through biomarkers ▪ Follow up: Days 0, 14, 30, 60 ▪ Hadassah Medical Center, Jerusalem Israel 	<ul style="list-style-type: none"> ▪ Well tolerated by all patients in all groups ▪ No systemic drug-related adverse events ▪ No changes in vital signs, serum biochemistry and hematological parameters during treatment or follow-up periods (30-days post-treatment) ▪ No changes in lymphocyte and CD+ cell counts ▪ No changes in weight or BMI or HbA1C lipid GLP-1, or CRP levels in any of the groups 	<ul style="list-style-type: none"> ▪ Increases in Treg markers consistent with induction of Tregs ▪ Anti-inflammatory markers ↑ ▪ CD4+CD25+LAP+ Treg cells, TGFβ1 <p style="font-size: small; margin-top: 10px;">Sources:1) Lalazar, G., Mizrahi, M., Turgeman, I., Adar, T., Ysi'Acov, A. B., Shebat, Y., ... Ilan, Y. (2015). Oral Administration of OKT3 Mab to Patients with NASH, Promotes Regulatory T-cell Induction, and Alleviates Insulin Resistance: Results of a Phase IIa Blinded Placebo-Controlled Trial. <i>Journal of Clinical Immunology</i>, 35(4), 399-407.</p>	<ul style="list-style-type: none"> ▪ Positive trends, some of which were statistically significant ▪ AST ↓ – liver enzyme indicating reduced liver inflammation ▪ Glucose ↓ – favorable for subjects with type-2 diabetes ▪ Insulin ↓ – favorable for subjects with type-2 diabetes

Milciclib

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A PAN-CDK INHIBITOR FOR
TREATMENT OF HEPATOCELLULAR
CARCINOMA AND SOLID TUMORS

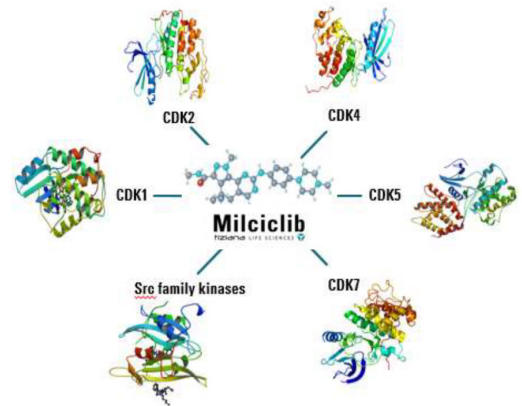
HCC is complex and heterogenous cancer associated with multiple etiological factors



Newer treatment approach with broad-spectrum action is needed to address heterogeneity of HCC

SMALL MOLECULE PAN-CDK INHIBITOR

- Complex heterogeneity in HCC due to multiple etiological agents; Need for broad-spectrum approach
- Orally-bioavailable small molecule with potent anti-tumor activity in a wide range of animal models
- Inhibitor of kinases associated with cancer cell growth including CDK1, CDK2, CDK4, CDK5, CDK7 and src-family kinases
- Inhibits signaling pathways for hepato-carcinogenesis
- Well tolerated in 316 patients
- Improved toxicity profile over the current standard of care anticipated



A drug with completely differentiated MOA and long-term safety

CLINICAL DATA FROM MILCICLIB

PHASE 2A TRIAL IN SORAFENIB-RESISTANT HCC PATIENTS

Trial design: Oral administration (100 mg/day, consecutive 4 days a week in a 4-week cycle). Total patients 30 to be enrolled. Duration 6 months

Primary end point: safety

Secondary end points: PFS, ORR & TTP

Exploratory: AFP and miRNA profiling

Compassionate use: Upon request of patients with EC approval

Trial complete: Data from 28 out of 31 evaluable sorafenib-resistant HCC patients

- 14 patients completed treatment as per protocol
- Nine approved for compassionate use. Seven patients completed 9, 9, 10, 11, 13, 13 and 16 months, respectively.
- **No drug related deaths in the trial**
- Treatment was well-tolerated
- Adverse events were manageable
- **Time to progression 5.9 months out of 6 months duration of trial**
- **Stabilized Disease (SD) 61%**
- **Clinical Benefit Response 64%**

Two patients currently continuing on compassionate use. Ongoing treatment at 16 months.

CLINICAL DATA SUGGEST MILCICLIB OVERCOMES GEMCITABINE RESISTANCE

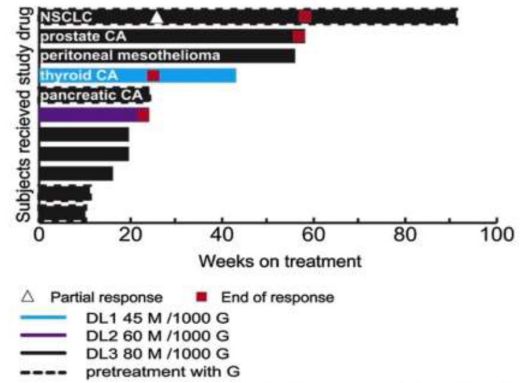
PATIENTS RAPIDLY ACQUIRE RESISTANCE TOWARDS CHEMOTHERAPIES

KEY FINDINGS FROM PHASE 1 STUDY

1. Milciclib **well-tolerated with manageable side effects in patients** with refractory solid tumors
2. Oral treatment in **combination with gemcitabine demonstrated clinical activity** in patients who were non-responder to existing chemotherapeutic drugs
3. Recommended Phase 2 dose (RPD) **found to be 80mg/m²/day for milciclib and 1000mg/m²/day for gemcitabine**
4. Overall **response rate was 36%**
5. Results **suggest further evaluation in other solid cancers either as monotherapy or combo-therapy**

Phase 1 Dose-Escalation Study of Milciclib in Combination with Gemcitabine in Patients with Refractory Solid Tumors*

Sandrine Aspeslagh¹ · Kunwar Shailubhai² · Rastlav Bahleda¹ · Anas Gazzah¹ ·
Andréa Varga¹ · Antoine Hollebecque¹ · Christophe Massard¹ · Anna Spreafico³ ·
Michele Reni³ · Jean-Charles Soria¹






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

INTELLECTUAL PROPERTY PORTFOLIO

FAMILY	SUBJECT	PRIORITY	STATUS	EXPIRES	JURISDICTION
Foralumab <small>tiziana LIFE SCIENCES</small> TZLS-401	Methods of Use (Autoimmune or Inflammatory diseases and disorders)	2004	Issued	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	Issued/ Pending	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 <u>Pending</u> : Japan (divisional), Singapore (divisional), US (divisional)
	Methods of Use (In combination with anti-IL-6/IL-6R antibodies)	2011	Pending	2032	US
	Formulations and dosing regimen	2016	Pending	2037	US (allowed), Australia, Canada, China, Europe, Hong Kong, Israel, Japan
	Methods of Use (CNS disorders)	2017	Pending	2038	National
	Methods of Use (gastrointestinal/autoimmune/inflammatory)	2018	Pending	2039	PCT
Milciclib <small>tiziana LIFE SCIENCES</small> TZLS-201	Composition of matter, methods of use, process of manufacturing	2003	Issued/ Pending	2024	US, Europe, 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, Tunisia, Ukraine, Uzbekistan, Vietnam. <u>Pending</u> : US, Brazil, Egypt, Thailand, Trinidad & Tobago, 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	2029; 2030	US, EU, China, Hong Kong, Japan
	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	Pending	2038	US, PCT
Anti IL-6/IL-6R Antibody TZLS-501	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. <u>Pending</u> : US (divisional), Japan (divisional)

UPCOMING CATALYSTS

PRODUCT	ACTION/OBJECTIVE	TARGET DATE
 Foralumab tiziana LIFE SCIENCES	Phase 2 trial with orally administered Foralumab in Crohn's Disease patients anticipated completion	Q4, 2020
 Foralumab tiziana LIFE SCIENCES	Phase 2 trial with nasally administered Foralumab in progressive multiple sclerosis (pro-MS) patients anticipated completion	Q1, 2021
 Milciclib tiziana LIFE SCIENCES	Initiate Phase 2b in HCC patients with Milciclib in combination with a TKI. This trial is anticipated to be completed Q4 in 2021	Q2, 2020

GROWTH OBJECTIVES

CAPITAL STRUCTURE

-
- Ordinary Shares
 - Warrants (WAEP: £4.75)
 - Options (WAEP: £8.25)
 - Convertible Notes as Converted**
-

Fully Diluted Shares

ADS EQUIVALENT*

-
- 27,330,903
 - 1,017,312
 - 3,426,881
 - 721,183
-

32,496,279

*Information prepared as of 10 January 2020. 1 ADS represents 5 ordinary shares.

** £1,514,493.92 notes convertible at £0.42

The Company is contemplating/planning to migrate to Bermuda in Q2 2020 to enable delisting from AIM, eliminate its ADR program and have Bermuda common shares on NASDAQ

Foralumab
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Milciclib
hizana LIFE SCIENCES

BACK UP SLIDES



FORALUMAB IS FUNCTIONALLY EQUIVALENT TO OKT3

Oral Treatment prevents skin xenograft rejection in mice with human immune systems

Mineko Ogura, Songyan Deng, Paula Preston-Hurlburt, Hideki Ogura, Kunwar Shailubhai, Chantal Kuhn, Howard L. Weiner, and Kevan C. Herold

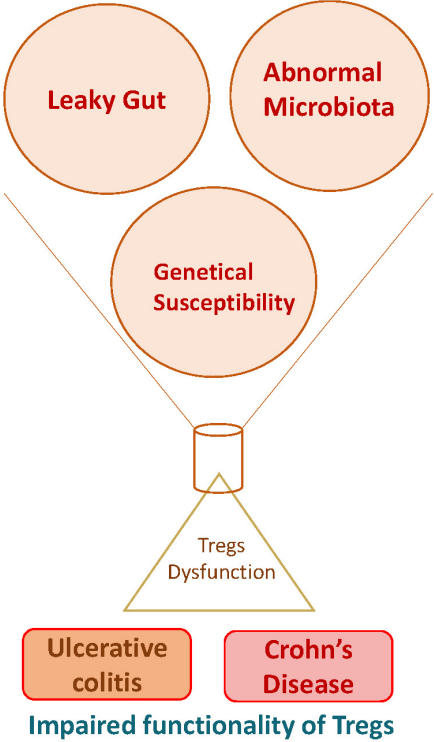
Clinical Immunol., 2017, 183: 240-246

KEY FINDINGS

1. Foralumab is as potent as OKT3
2. Treatment is **effective in humanized mice studies**
3. Mechanism of action is via **activation of Tregs that systemically circulate to elicit targeted immunomodulation**

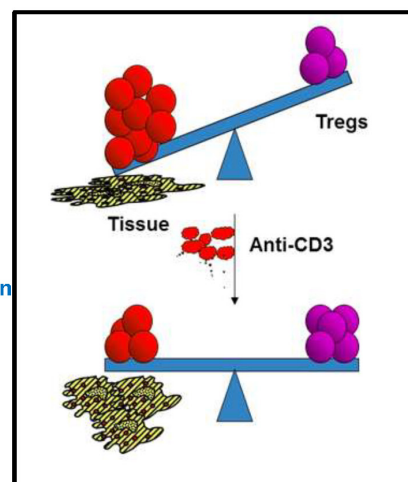


Oral Administration of Foralumab is Expected to Stimulate Tregs Through Activation of Gut Mucosal Immunity



Anti-CD3 Monoclonal Antibodies Induce Regulatory T Cell (T reg) for the Treatment of Autoimmune and Inflammatory Diseases

- Potential for treatment of Type 1 diabetes is well established
- Preservation/protection of β -cells is demonstrated in pre-clinical studies
- Improved insulin resistance and glucose tolerance in Type 2 diabetes by induction of T regs
- Anti-CD3's show potential in preventing graft versus host disease (GvHD) in hematopoietic stem cell transplantation (HSCT) via induction of T regs
 - Patients with renal allograft rejection dosed IV with foralumab, delayed graft rejection and improved renal function
 - **Foralumab shows promise for successful stem cell/CAR-T transplantation**
- Anti-CD3 mediates immune tolerance by
 - induction of T regs
 - mediated by IL-10 (nasal tolerance) and TGF- β and LAP complex leading to differentiation of T cells to T regs (oral tolerance)
 - LFA-1 (cell adhesion molecule critical for T reg homeostasis and function)
- Induces apoptosis of effector T cells to normalize balance of Treg:Teff cells ratio



Anti-CD3 antibody increases T reg:Teff ratio

POTENTIAL TO TREAT TYPE 1 DIABETES

New England Journal of Medicine* provides clinical evidence for the potential use of a humanized anti-CD3 mAb for treatment of type 1 diabetes

KEY FINDINGS

1. Teplizumab (humanized OKT3), administered intravenously, **significantly slowed progression to clinical Type 1 diabetes, with a median delay in the diagnosis of diabetes of 2 years**
2. At the end of the trial, **57% of subjects treated with Teplizumab showed slowed progression to development of Type 1 diabetes, while 72% of the placebo-treated subjects progressed to clinical diabetes**



*K. Herold, B. Bundy, S.A. Long, J. Bluestone, L. Dimeglio, M. Dufort, S. Gitelman, P. Gottlieb, J. Krischer, P. Linsley, J. Marks, W. Moore, A. Moran, H. Rodriguez, W. Russell, D. Schatz, J. Skyler, E. Tsalkian, D. Wherrett, A-G. Ziegler and C. Greenbaum. "An Anti-CD3 Antibody, Teplizumab, in Relatives at Risk for Type 1 Diabetes," epub NEJM.org June 9 2019

THYMIC CARCINOMA AND THYMOMA UPDATES

- Two Phase 2 trials with Milciclib in US, Italy and France
 - Trial 006: Thymic carcinoma and Thymoma mixed population (72 patients)
 - Trial 007: Thymic carcinoma and Thymoma mixed population (30 patients)
- Rare cancers with very few cases: Orphan Disease Indications
- Positive clinical data
- **Primary endpoint (progression free survival) and secondary endpoint (overall survival) met in both trials separately**
- Thymic carcinoma is an aggressive metastatic cancer and it has no approved therapy
- Milciclib as a single agent met primary as well as secondary endpoints in thymic carcinoma in both trials
- **Under compassionate use, few patients continued the treatment for over five years**
- Seeking guidance from FDA/EMA regarding conditional marketing approval



An Innovative Platform in Oral and Nasal Antibody Administration

A Distinct Approach for Treatment of Hepatocellular Carcinoma

Foralumab
tiziana LIFE SCIENCES

Milciclib
tiziana LIFE SCIENCES

TLSA: NASDAQ **TILS: AIM**

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