

Tiziana Life Sciences Ltd Reports Annual Results for the Twelve Months Ended December 31, 2022, and Corporate Update

NEW YORK, April 26, 2023 – Tiziana Life Sciences, Ltd. (Nasdaq: TLSA) (“Tiziana” or the “Company”), a biotechnology company developing breakthrough immunomodulation therapies via novel routes of drug delivery, today announced financial results for the twelve months ended December 31, 2022, and provided a corporate update on its lead programs in development.

Gabriele Cerrone, Executive Chairman, founder and interim Chief Executive Officer of Tiziana, commented, “After announcing our focus on advancing intranasal foralumab to address CNS-mediated inflammatory diseases, we have started this year with a stream of continuous, positive program-related developments. Intranasal foralumab’s unique action on regulatory T-cells and its potential to treat multiple inflammatory pathology indications has been published in a major medical journal and recognized in the media. We also recently announced intranasal foralumab’s potential to treat Long Covid, Alzheimer’s and Type 1 diabetes. Our near-term strategic focus is to prioritize resources for the clinical development of this unique therapeutic candidate to maximize shareholder value while still maintaining optionality for our other research programs, including milciclib in oncology. We aim to become a leading company pioneering intranasal therapies for inflammatory diseases”.

Fourth Quarter 2022 Developments Related to Foralumab

In October:

- Tiziana announced that it plans to submit an Investigational New Drug Application (IND) for a Phase 1 Trial of intranasal foralumab in Alzheimer’s disease patients after receiving an affirmative written response from the FDA on a Pre-Investigational New Drug Application (PIND). Tiziana plans on filing the IND for Alzheimer’s disease by the second quarter of 2023 upon the completion of requested toxicology studies.

In November:

- Tiziana announced publication of a scientific article in the peer-reviewed journal *Frontiers in Immunology* entitled “**Nasal administration of anti-CD3 monoclonal antibody modulates effector CD8+ T cell function and induces a regulatory response in T cells in human subjects**” ⁽¹⁾. The study was completed by researchers at the Brigham and Women’s Hospital (BWH) and Harvard Medical School. The goal of the study was to assess safety and the immune effects of an entirely human, previously uncharacterized nasal anti-CD3 mAb (foralumab) in humans and its *in vitro* stimulatory properties. The findings support Tiziana’s intranasal foralumab platform as a new modality for the treatment of autoimmune and CNS diseases.

- Tiziana announced a corporate update, including its near-term focus on developing intranasal foralumab for inflammatory diseases of the Central Nervous System (CNS) such as non-active secondary-progressive Multiple Sclerosis (SPMS), Alzheimer’s disease and amyotrophic lateral sclerosis (ALS).
- Tiziana announced completion of enrollment of the first patient cohort (n=4) in its Intermediate-Size Patient Population Expanded Access Program to evaluate foralumab in non-active Secondary Progressive Multiple Sclerosis (SPMS).

In December:

- Tiziana announced completion of the in-life portion of a 13-week, Good Laboratory Practice (GLP) foralumab intranasal pre-clinical study in transgenic HuGEMM CD3 mouse models. The study showed that intranasal foralumab, administered to the transgenic mice at doses up to 50 µg/rodent, was clinically well tolerated.

2023 Recent Clinical Program Updates

In January:

- Tiziana announced that the second patient in its Expanded Access trial (“EA2”) with non-active secondary progressive multiple sclerosis (SPMS) receiving intranasal foralumab showed additional clinical improvements since his last reported improvement in September 2022. The improvements were measured by the Expanded Disability Status Scale (EDSS), a U.S. Food and Drug Administration (FDA) - recognized standard clinical outcome assessment.

In March:

- Tiziana announced a publication in the preeminent¹ journal, *Proceedings of the National Academy of Sciences* (PNAS), that illustrates the immunological basis of the mechanism of action (MoA) for intranasal foralumab. The publication highlights that the immunological basis of the mechanism of action for intranasal foralumab is based on increasing production of naïve-like T cells and Tregs, while simultaneously decreasing the production of effector T cells. Further, the publication demonstrates that intranasal foralumab has similar immune gene expression effects in COVID patients, MS patients and in healthy volunteers. The study concludes that immunomodulation by nasal anti-CD3 mAb represents a novel avenue for treatment of inflammatory human diseases. A copy of the publication can be found at pnas.org.²
 - As a result of this publication, Dr. Tanuja Chitnis, M.D., Professor of Neurology at Brigham Women’s Hospital, a founding member of Mass General Brigham Healthcare System, and lead investigator of the study, noted that foralumab also “makes a promising therapeutic candidate for

several rare Orphan pediatric neuroinflammatory diseases, which currently remain untreated.”

- Tiziana announced its intention to start a Phase 2 study in the third quarter of 2023 in patients with non-active Secondary Progressive Multiple Sclerosis (SPMS) employing intranasal foralumab.
- Tiziana announced data from a pre-clinical study on the effects of intranasal foralumab in Alzheimer's disease which were presented on April 1, 2023, at the International Conference on Alzheimer's and Parkinson's Disease and Related Neurological Disorders by Dr. Howard Weiner, M.D., Co-Director of the Ann Romney Center for Neurologic Diseases at Brigham and Women's Hospital. The data showed reduction of microglia activation and improvement in behavior in animal models of Alzheimer's disease.
- Additionally, Tiziana's foralumab was highlighted in a [Forbes magazine article](#) entitled "*New T Cell Antibody Treatment Improves Outcomes for Covid Patients*" authored by contributing author, thought leader and pioneer in genomic sciences, [William A. Haseltine](#) who stated "*Foralumab induces many factors that impact improved tissue remodeling, induction of immune cells, and restriction of effector function, improving disease outcomes while fighting the virus to full strength. These benefits are not limited to Covid-19 patients, as similar results were observed in patients with multiple sclerosis.*"

In April:

- Tiziana announced data from a pre-clinical study on the effects of intranasal foralumab in intracerebral hemorrhage (hemorrhagic stroke) that demonstrated one-month behavioral outcomes improvement and modulation of neuroinflammation. These data were presented in a podium presentation by Dr. Saef Izzy, M.D., MBCHB, Assistant Professor of Neurology at Harvard Medical School on April 23, 2023, at the American Academy of Neurology (AAN) annual meeting.
- Tiziana plans to investigate intranasal foralumab for the treatment of Long COVID. The work is supported by foralumab's well-established role in de-activating microglia cells, a key component in the pathogenesis of this disease. The Company anticipates entering into a Phase 2a, placebo-controlled, clinical trial upon successful feedback from the FDA.
- Tiziana Life Sciences to file Alzheimer's IND for intranasal foralumab in the second quarter of 2023. Additionally, an application for \$3M of non-dilutive funding to

support a Phase 2a Alzheimer's trial will be submitted in the second quarter of 2023 with a response expected in the third quarter of 2023.

- Tiziana also announced that it is initiating a program to develop intranasal foralumab for the treatment or delay of Type 1 Diabetes.

2022 Year End Financial Results

- For the twelve months ended 31 December 2022 Tiziana reported a loss of \$19.0 million compared to \$27.9 million in the twelve months ended 31 December 2021.
- Research and development (R&D) expenses decreased to \$13.0 million compared to \$13.2 million in the twelve months ended 31 December 2021. The decrease is primarily related to the focus on the Company's proprietary programs, foralumab and to a lower extent, IL6-R.
- Tiziana ended the period with \$18.1 million cash as of 31 December 2022 as compared to \$42.2 million on 31 December 2021.

Tiziana's Annual Report on Form 20-F can be accessed by visiting either the SEC's website at www.sec.gov or the Investors section of the Company's website at ir.tizianalifesciences.com/financial-information/annual-reports.

[1] <https://www.pnas.org/about/article-journal-metrics>

[2] <https://www.pnas.org/doi/10.1073/pnas.2220272120>

About Foralumab

Activated T cells play an important role in the inflammatory process. Foralumab, the only fully human anti-CD3 monoclonal antibody (mAb), binds to the T cell receptor and dampens inflammation by modulating T cell function, thereby suppressing effector features in multiple immune cell subsets. This effect has been demonstrated in patients with COVID and with multiple sclerosis, as well as in healthy normal subjects. Intranasal foralumab Phase 2 trials are expected to start in the third quarter of 2023 in patients with non-active SPMS. Immunomodulation by nasal anti-CD3 mAb represents a novel avenue for treatment of inflammatory human diseases.^[1]

About Tiziana Life Sciences

Tiziana Life Sciences is a clinical-stage biopharmaceutical company developing breakthrough therapies using transformational drug delivery technologies to enable alternative routes of immunotherapy. Tiziana's innovative nasal approach has the potential to provide an improvement in efficacy as well as safety and tolerability compared to intravenous (IV) delivery. Tiziana's lead candidate, intranasal foralumab,

which is the only fully human anti-CD3 mAb, has demonstrated a favorable safety profile and clinical response in patients in studies to date. Tiziana's technology for alternative routes of immunotherapy has been patented with several applications pending and is expected to allow for broad pipeline applications.

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