Tiziana Life Sciences Announces Study Results from Intranasal Anti-CD3 Foralumab in Multiple Sclerosis Patients with PIRA Highlighted in *Neurology Today*®

- *Intranasal foralumab attenuated microglial activation in patients with non-active secondary progressive multiple sclerosis and progression independent of relapse (PIRA) -*
- *Data presented in a platform session at the Annual Meeting of the American Academy of Neurology in Denver, Colorado -*

NEW YORK, April 19, 2024 – 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 that a study related to its lead candidate, foralumab, was highlighted in *Neurology Today®, the official news source of the American Academy of Neurology (AAN)*, in an article titled, "Anti-CD3 Antibody Foralumab Shows Promise in PIRA, Measured by Novel PET Ligand".

The study is authored by Tarun Singhal, M.B.B.S., M.D., Director, PET Imaging Program in Neurologic Diseases at Brigham and Women's Hospital, a founding member of Mass General Brigham Healthcare System, and Associate Professor of Neurology at Harvard Medical School, and shows that foralumab, a fully human anti-CD3 monoclonal-antibody, attenuates microglial activation in non-active secondary progressive multiple sclerosis (na-SPMS) patients with progression independent of relapse (PIRA). A systemic review published in *JAMA Neurology*[1] in October 2023 found that PIRA is the most frequent manifestation of disability accumulation across the full spectrum of traditional multiple sclerosis (MS) phenotypes.

"PIRA is a condition that poses a major unmet need for patients with multiple sclerosis," stated Dr. Singhal. "Currently, there are no disease-modifying therapies approved for this category of progressive MS patients. This study provides initial evidence that this fully human anti-CD3 has the potential to benefit this type of MS, which is the most difficult form to treat."

"We do not have any recognized approaches to try to alter microglial activation at present, which everyone agrees at this point in time is relevant throughout the life of a

patient with MS. Even ocrelizumab [Ocrevus] for primary progressive MS has modest impact, so the potential here is great, and the proof of principle that you can alter the microglia is a real punchline." said John Corboy, MD, FAAN, an endowed chair in neurology and director of the Rocky Mountain Multiple Sclerosis Center at the University of Colorado Anschutz Medical Campus.

The study assesses the effect of intranasal foralumab on microglial activation in na-SPMS patients with PIRA as measured by positron emission tomography (PET) imaging via radiology marker [F-18]PBR06-PET, a novel, long-half-life ligand used in PET scanning. The study is designed to be open-label and is based on data from the Expanded-Access Program evaluating foralumab in na-SPMS patients that is currently underway. In this study, five of six patients (83%, 95% confidence interval 44%-97%) showed a qualitative reduction on [F-18]PBR06-PET in multiple brain regions after both 3 and 6 months of nasal foralumab treatment.

Data from the study was presented at a platform session at the Annual Meeting of the American Academy of Neurology being held in Denver, Colorado. The abstract is entitled, “Treatment of PIRA with Nasal Foralumab Dampens Microglial Activation and Stabilizes Clinical Progression in Non-Active Secondary Progressive MS.

The link to the full *Neurology Today*® article can be found here: https://journals.lww.com/neurotodayonline/blog/NeurologyTodayConferenceReportersAANAnnualMeeting/pages/post.aspx?PostID=211

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. The non-active SPMS intranasal foralumab Phase 2 trial began screening patients in November of 2023. Immunomodulation by nasal anti-CD3 mAb represents a novel avenue for treatment of neuroinflammatory and neurodegenerative human diseases.[2],[3]

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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[1]Muller, M.D., J., Cagol, M.D., A., Lorschieder, M.D., J.; Harmonizing Definitions for Progressions Independent of Relapse Activity and Multiple Sclerosis: *JAMA Neurol.* 2023;80(11):1232-1245. doi:10.1001/jamaneurol.2023.3331

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

[3] https://www.pnas.org/doi/10.1073/pnas.2309221120