Tiziana Life Sciences Doses First Patient in Phase 2a Trial of Intranasal Foralumab in Multiple Sclerosis

NEW YORK, December 19, 2023 -- Tiziana Life Sciences Ltd. (Nasdaq: TLSA) ("Tiziana" or the "Company"), a biotechnology company developing breakthrough neuro-immunomodulation therapies, today announced "first patient dosed" in its Phase 2a study comparing two doses of intranasal foralumab and placebo in patients with non-active secondary-progressive multiple sclerosis (na-SPMS). Six investigational centers have been recruited for this double-blind, placebo-controlled trial, with up to 18 patients per treatment arm. The primary endpoint of the trial will be the change in microglial activation based on PET scans. Clinical evaluations include the Expanded Disability Status Scale (EDSS), QoL assessments, and the Modified Fatigue Impact Scale (MFIS), which assess parameters that are essential to a patient's everyday life. Novel immuno-biomarkers will be measured also and assessed for predictive relevance. Central review of PET scans and images is an integral component of this study.

"The successful consenting, screening, completion of the baseline PET scan, and dosing of our first patient in the intranasal foralumab Phase 2a trial has occurred seamlessly," said Tanuja Chitnis, M.D., the Principal Investigator at Brigham and Women's Hospital, a founding member-hospital of Mass General Brigham Healthcare System, and Professor of Neurology at Harvard Medical School. "My anticipation is this randomized placebo-controlled trial is the first step in bringing this potential treatment to patients that have na-SPMS, a disease with no approved therapy. Our experience in the Expanded Access Program provides sustainable hope for relief of symptoms in these patients with an unmet medical need."

Gabriele Cerrone, Chairman, acting CEO and founder of Tiziana Life Sciences said, "I believe that our dosing of the first patient confirms Tiziana's ability to execute on its commitments and potential to advance our fully human intranasal anti-CD3 mAb, foralumab, using novel imaging methods and clinically relevant endpoints. We hope our efforts will give a new therapeutic option to patients afflicted with this devastating disease. Currently, there are no FDA approved treatments for na-SPMS."

Matthew W. Davis, MD, RPh, Chief Operating Officer and Chief Medical Officer of Tiziana, added, "I am very pleased the first patient has been dosed and our team is committed to remaining on track with our milestones. We are poised to accelerate enrollment and anticipate data readout in Q4 2024. I believe the study results will

reveal important aspects for optimizing clinical management of na-SPMS - particularly the potential for a reduction in MFIS scores."

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 dosed its first patient in December of 2023. Immunomodulation by nasal anti-CD3 mAb represents a novel avenue for treatment of neuroinflammatory and neurodegenerative human diseases.[1,2]

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.

References:

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

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

Forward-Looking Statements

Certain statements made in this announcement are forward-looking statements. These forward-looking statements are not historical facts but rather are based on the Company's current expectations, estimates, and projections about its industry, its beliefs, and assumptions. Words such as 'anticipates,' 'expects,' 'intends,' 'plans,' 'believes,' 'seeks,' 'estimates,' and similar expressions are intended to identify forward-looking statements. These statements are not guarantees of future performance and are subject to known and unknown risks, uncertainties, and other factors, some of which are beyond the Company's control, are difficult to predict, and could cause actual results to differ materially from those expressed or forecasted in the forward-looking statements. The Company cautions security holders and prospective security holders not to place undue reliance on these forward-looking statements, which reflect the view of the Company only as of the date of this announcement. Actual results may differ

materially from those indicated by such forward-looking statements as a result of various important factors, including: the uncertainties related to market conditions and other factors described more fully in the section entitled ‘Risk Factors’ in Tiziana’s Annual Report on Form 20-F for the year ended December 31, 2022, and other periodic reports filed with the Securities and Exchange Commission.The forward-looking statements made in this announcement relate only to events as of the date on which the statements are made. The Company will not undertake any obligation to release publicly any revisions or updates to these forward-looking statements to reflect events, circumstances, or unanticipated events occurring after the date of this announcement except as required by law or by any appropriate regulatory authority.

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