Tiziana Life Sciences Announces FDA Allowance for Additional Twenty Patients to be Enrolled in the Intranasal Foralumab Multiple Sclerosis Expanded Access Program

NEW YORK, April 23, 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 the U.S. Food and Drug Administration (FDA) has allowed its intranasal foralumab non-active Secondary Progressive Multiple Sclerosis (na-SPMS) Expanded Access (EA) Program to expand from 10 patients to a total of 30 patients.

To date, of the 10 participating patients, two patients have been dosed for more than one year and eight additional patients have been dosed for six months, all without serious side effects. All patients have either stabilized or improved on treatment with foralumab, and no patients have declined in key clinical measures. Additionally, 70% of these patients have seen a measurable improvement in fatigue. These data are the first to combine PET imaging with a novel ligand, immune-biomarkers, clinical measures and comprehensive safety data endpoints in patients receiving long-term intranasal foralumab. In November 2023 Tiziana initiated a Phase 2a trial in na-SPMS. Patients not eligible for the Phase 2a trial may now be considered for this expanded EA program.

The September 2023 release of FDA guidance entitled "Guidance on Substantial and Confirmatory Evidence of Efficacy and Safety" addresses the use of EA programs to be considered as part of confirmatory evidence. As per FDA guidance, "Expanded access refers to the use of an investigational drug when the primary purpose is to diagnose, monitor, or treat a patient's disease or condition rather than to obtain the kind of information about the drug that is generally derived from clinical trials."

Gabriele Cerrone, Chairman, acting CEO and founder of Tiziana Life Sciences commented, "Tiziana is glad to provide patients with na-SPMS who do not qualify to be enrolled on our Phase 2 trial (NCT06292923) the possibility to receive open-label treatment with our intranasal fully human anti-CD3 monoclonal-antibody, foralumab. As there are no FDA approved treatments for na-SPMS, an EA program gives these patients access to this novel drug."

“I am grateful to be allowed to dose 20 additional patients that do not meet the inclusion criteria for the ongoing intranasal foralumab Phase 2a, randomized, double-blind placebo-controlled, multicenter dose-ranging study multiple sclerosis trial potential access to this treatment,” stated Dr. Tanuja Chitnis, M.D., Professor of Neurology at Harvard Medical School and senior neurologist at Brigham and Women’s Hospital, a founding member of Mass General Brigham Healthcare System. “The EA program has allowed us to obtain important information about dosing, and drug use, including patient feedback which was critical for the design of the current Phase 2a trial.”

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 na-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.[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.

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

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