



Tiziana Life Sciences Announces Updated Clinical and PET Scan Findings for Intranasal Foralumab in Two New Multiple Sclerosis Patients

NEW YORK, January 08, 2024 -- Tiziana Life Sciences Ltd. (Nasdaq: [TLSA](#)) (“Tiziana” or the “Company”), a biotechnology company developing breakthrough neuro-immunomodulation therapies, today announced positive findings have been seen in a total of six out of eight Intermediate Size Patient Population Expanded Access (EA) patients. These patients have shown improvements in fatigue scores measured by the Modified Fatigue Impact Scale (MFIS). PET scan findings showing a reduction in microglial activation was also seen in the six patients with MFIS score improvement at the three-month evaluation period. PET scan findings for two additional EA patients (10 total) are planned to be available in late January.

Tarun Singhal, M.B.B.S., M.D., Director of 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, commented, “Upon review of the baseline and three-month [F-18] PBR06 PET scans of the two new na-SPMS EA patients, a qualitative reduction in microglial activity was seen in one of two new patients. When combined with my assessment of the first six EA patients at three-months, a total of six out of the eight suggested a reduction in qualitative microglial PET signal. These findings are promising from an imaging standpoint and further studies are needed to confirm them using additional quantitative approaches.”

“The EA patient having a qualitative improvement in their PET scan also improved in their Modified Fatigue Impact Scale,” stated Dr. Tanuja Chitnis, M.D., Principal Investigator and Professor of Neurology at Harvard Medical School and senior neurologist at Brigham and Women’s Hospital. “Six out of the eight na-SPMS EA patients studied so far have seen measurable clinical improvement in their fatigue. I am excited to lead the effort to replicate these findings in the ongoing Phase 2 dose-ranging, randomized, placebo-controlled clinical trial.”

Gabriele Cerrone, Chairman, acting CEO and founder of Tiziana Life Sciences noted “We’ve seen continued clinical and qualitative PET scan improvement over time in patients with na-SPMS where intranasal foralumab targets inflammation in the brain. It is my expectation that we will rapidly progress our ongoing Phase 2 trial of intranasal foralumab, given the encouraging results seen so far under the EA IND

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.

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

¹ <https://www.pnas.org/doi/10.1073/pnas.2220272120>

² <https://www.pnas.org/doi/10.1073/pnas.2309221120>

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.

For further inquiries:

Tiziana Life Sciences Ltd

Paul Spencer, Business Development and Investor Relations

+44 (0) 207 495 2379

email: info@tizianalifesciences.com

Investors:

Irina Koffler

LifeSci Advisors, LLC

+1 646 970 4681

ikoffler@lifesciadvisors.com