Tiziana Announces Positive Qualitative Six-Month PET Scan Results With Intranasal Foralumab Treating Multiple Sclerosis Patients Diagnosed With Non-Active Secondary Progressive MS (na-SPMS)

- Five out of six patients in FDA authorized Expanded Access Program are showing a qualitative reduction in microglia activation (a key biomarker being observed)
- Foralumab to advance into Phase 2 human clinical trials using the world's only fully human intranasal anti-CD3 monoclonal antibody
- Phase 2 trial screening for na-SPMS to begin in November 2023

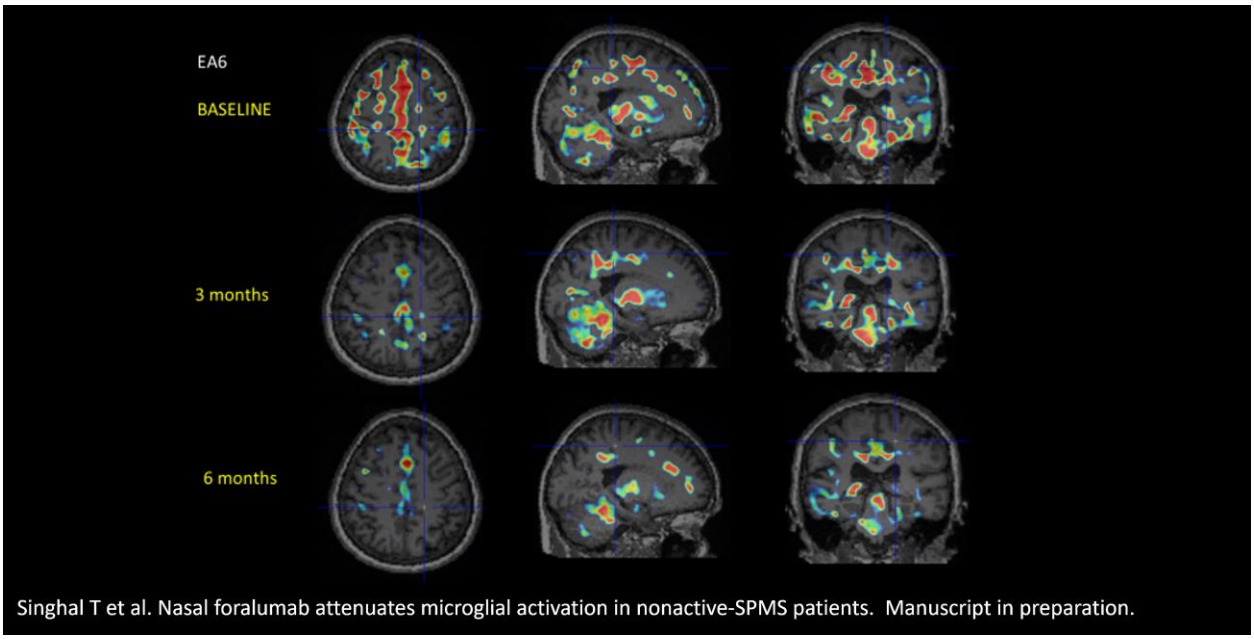
NEW YORK, October 13, 2023 -- Tiziana Life Sciences Ltd. (Nasdaq: TLSA) ("Tiziana" or the "Company"), a biotechnology company developing breakthrough immunomodulation therapies via novel routes of drug delivery, today announced that a reduction in activated microglia, as seen in six-month Positron Emission Tomography (PET) scans, has now been observed in a total of five of the six patients with non-active secondary-progressive multiple sclerosis (na-SPMS) treated with intranasal foralumab in its Expanded Access Program (EAP). Activated microglia are believed to play a prominent role in the pathogenesis of neuroinflammatory and neurodegenerative diseases including multiple sclerosis, Alzheimer's disease, and amyotrophic lateral sclerosis, or ALS.

Tarun Singhal, M.B.B.S., M.D., Director of the PET Imaging Program in Neurologic Diseases, associate neurologist and nuclear medicine physician at Brigham and Women's Hospital, a founding member of Mass General Brigham Healthcare System, and Assistant Professor of Neurology at Harvard Medical School, commented, "Upon review of the baseline and six-month PET scans of the latest cohort of four Expanded Access patients, three out of the four scans suggested a qualitative reduction in the microglial PET signal. When combined with my assessment of the first two Expanded Access patients at six-months, five of the six suggested a reduction in qualitative microglial PET signal. An example of this can be seen in the graphic below, titled, "Figure 1", showing the deactivation of this signal in patient EA6. This is promising from an imaging standpoint, and further studies are needed to confirm these findings using additional quantitative approaches."

Howard L. Weiner, M.D., Chairman of Tiziana's Scientific Advisory Board and Co-Director of the Ann Romney Center for Neurologic Diseases at Brigham and Women's Hospital added, "With six patients now dosed in our na-SPMS EA program, I feel that Dr. Singhal's readout of the six-month PET scans strongly supports our previously announced 3-month clinical findings."

Gabriele Cerrone, Chairman, acting CEO and founder of Tiziana Life Sciences commented, "I believe that the six-month qualitative na-SPMS PET readout by Dr. Singhal is very encouraging and will enable us to rapidly advance foralumab in Phase 2a testing to address patients afflicted with this devasting disease who currently have no FDA-approved treatments available."

Figure 1.



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 is expected to start screening 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.

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[1] https://www.pnas.org/doi/10.1073/pnas.2220272120
[2] https://www.pnas.org/doi/10.1073/pnas.2309221120