



Tiziana Life Sciences Initiates Multi-Center Phase 2a Clinical Trial of Intranasal Foralumab for Non-Active Secondary Progressive Multiple Sclerosis

NEW YORK, September 26, 2023 – Tiziana Life Sciences Ltd. (Nasdaq: [TLSA](#)) (“Tiziana” or the “Company”), a biotechnology company developing breakthrough immunomodulation therapies via novel routes of delivery, today announced that it held an Investigator’s Meeting with principal investigators at Brigham and Women’s Hospital, a founding member of Mass General Brigham Healthcare System, to begin site initiation for its lead intranasal foralumab program entering Phase 2a clinical testing in non-active Secondary Progressive Multiple Sclerosis (na-SPMS) patients. In total, six to ten new clinical trial sites will be recruited.

Matthew W. Davis, M.D., RPh, Chief Operating Officer and Chief Medical Officer of Tiziana Life Sciences, stated, “As planned for this quarter, we are on track and have begun site initiation visits so patient enrollment begins in this critical clinical trial. Advancing our lead anti-CD3 therapeutic, foralumab, in na-SPMS into Phase 2a will enable Tiziana to define novel endpoints, such as PET imaging, a similar target endpoint in our Expanded Access program (EAP). We are encouraged as five out of six patients in our open-label EAP have improved by qualitative analysis in their PET scans (3 months of treatment) compared to baseline. Phase 2a na-SPMS study assesses the same outcome measure, but now, and for the first time for this novel therapeutic, in a double-blind, randomized placebo control, a multi-center trial is now underway.

About Foralumab

Activated T cells play a critical 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, suppressing effector features in multiple immune cell subsets. This effect has been demonstrated in patients with COVID-19, multiple sclerosis, and healthy, normal subjects. Intranasal foralumab Phase 2 trials have begun in patients with non-active SPMS. Nasal anti-CD3 mAb represents a novel avenue for treatment of neuroinflammatory and neurodegenerative human diseases.^{1,2}

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

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

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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