# Tiziana Life Sciences to Proceed with Phase 2 Clinical Trial in Patients with Non-Active Secondary Progressive Multiple Sclerosis (SPMS)

# FDA Provides Positive Feedback on Intranasal Foralumab Program in Patients with Non-Active SPMS

- **First Phase 2 trial employing intranasal foralumab for treating inflammatory neurological disease**
- **Tiziana received FDA Type C Meeting Minutes for proposed Phase 2 clinical trial in patients with non-active SPMS**
- **Phase 2 protocol to be submitted to the FDA in April**
- **Phase 2 clinical trial expected to start in Q3 2023**

NEW YORK, March 28, 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 it has received feedback based on the U.S. Food and Drug Administration (FDA) Type C meeting minutes related to the Phase 2 clinical trial of intranasal foralumab in patients with non-active SPMS. Tiziana plans to accept the FDA's recommendations and intends to start a Phase 2 study in the third quarter of 2023 as previously announced. Foralumab is the only fully human anti-CD3 monoclonal antibody (mAb).

"Tiziana has reached an important regulatory milestone as it proceeds with the first ever intranasal foralumab clinical trial," commented Gabriele Cerrone, Executive Chairman and interim Chief Executive Officer. "The FDA's response to our proposed Phase 2 program allows Tiziana's to advance foralumab through the regulatory process as we strive to bring this novel treatment to patients with non-active SPMS."

"I am grateful for the FDA's thoughtful review of our Phase 2 plans for intranasal foralumab," stated Matthew W. Davis, M.D., RPh, Chief Medical Officer. "This upcoming quarter, we will update the Phase 2 protocol with the FDA's suggestions and

plan to start the Phase 2 clinical trial by holding our first investigator's meeting in Q3 2023."

**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. Intranasal foralumab Phase 2 trials are expected to start in the third quarter of 2023 in patients with non-active SPMS. Immunomodulation by nasal anti-CD3 mAb represents a novel avenue for treatment of inflammatory human diseases.[1]

**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