Tiziana Life Sciences to File Alzheimer's IND for Intranasal Foralumab in Q2 2023

- **Application for $3M of non-dilutive funding for Phase 2a Alzheimer's trial will be submitted in Q2 2023**
- **Tiziana guided by FDA Type "B" meeting comments on its scheduled Q2 2023 intranasal foralumab Alzheimer's IND filing**
- **Alzheimer's patients will be administered 3-months of intranasal foralumab to study effects on neuroinflammation caused microglia activation**

NEW YORK, April 20, 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 its plan to submit an IND for intranasal foralumab in patients with mild to moderate Alzheimer's Disease in Q2 2023.

"Following the FDA feedback from our protocol and development plans from the August 2022 type "B" Pre-IND meeting, Tiziana plans submit its intranasal foralumab protocol and IND for mild to moderate Alzheimer's disease in Q2 2023," stated Gabriele Cerrone, Executive Chairman, Founder and interim Chief Executive Officer of Tiziana. "Tiziana is also seeking $3,000,000 in non-dilutive funding from a prestigious Alzheimer's foundation to support the Phase 2a trial. It is my expectation that this funding application will be submitted Q2 2023 with a response expected Q3 2023."

"There are no FDA approved treatments for Alzheimer's disease specific to the neuroinflammation caused microglia activation triggered by amyloid beta plaque," commented Matthew W. Davis, M.D., RPh, Chief Medical Officer of Tiziana. "We plan to study 3-months administration of intranasal foralumab in Alzheimer's disease patients to see if neuroinflammatory activated microglia will return to the baseline homeostatic state."

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.**Error! Bookmark not defined.**

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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