Tiziana Life Sciences Announces Foralumab Dosing of Four New Patients in the Expanded Access Program for Multiple Sclerosis

NEW YORK, November 30, 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 the company has successfully enrolled and dosed four new patients with non-active secondary progressive multiple sclerosis (na-SPMS) in the Brigham and Women's Hospital, a founding member of Mass General Brigham Healthcare System Expanded Access (EA) Program. A total of ten patients are now being followed in the EA Program.

The Intermediate Size EA Program for na-SPMS represents a critical step forward in Tiziana Life Sciences' mission to provide treatment options for patients living with this debilitating disease while collecting valuable regulatory evidence about this novel investigational therapy. The EA program with foralumab, a fully human anti-CD3, has allowed Tiziana to obtain information about dosing, and drug use, including patient feedback which is critical for the design of future studies. The September 2023 release of FDA guidance entitled "Guidance on Substantial and Confirmatory Evidence of Efficacy and Safety" addresses the use of EA programs to be considered as part of confirmatory evidence. To date, two patients have been dosed for more than one year and four additional patients have been dosed for six months, all without serious side effects. These data are the first to combine imaging, immune-biomarkers, and clinical measures and safety data endpoints in patients receiving long-term intranasal foralumab. Tiziana recently initiated a Phase 2a trial in na-SPMS. Patients not eligible for the Phase 2a trial may be considered for the EA program.

"We are pleased to announce the commencement of dosing in the second intermediate-sized patient cohort for our na-SPMS Expanded Access Program," said Gabriele Cerrone, Chairman, acting CEO and founder of Tiziana Life Sciences. "Our dedication to advancing the field of multiple sclerosis research and providing patients with innovative treatment options is unwavering. Additionally, the anticipated enrollment of our first patient in the Phase 2a na-SPMS trial this month brings us another step closer to fulfilling our mission of improving the quality of life for individuals living with na-SPMS."

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 trial is ongoing in patients with non-active SPMS. 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.

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

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