Tiziana Life Sciences Announces Allowance By FDA For At-Home Dosing Of Intranasal Foralumab For Multiple Sclerosis Treatment

- Patients In the Intermediate Size Patient Population Expanded Access (EA) Program Will Receive Intranasal Foralumab As Part of the At-Home Dosing Initiative
- Greater Than 1 year Safety Exposure to anti-CD3 Foralumab Has Been Well-Tolerated
- At-Home Dosing Likely to Improve Patient Compliance to Treatment and Outcomes

NEW YORK, October 18, 2023 --Tiziana Life Sciences Ltd. (Nasdaq: TLSA) ("Tiziana" or the "Company"), a biotechnology company developing breakthrough immunomodulation therapies via novel routes of drug delivery, is pleased to announce a significant milestone in the treatment of multiple sclerosis. The U.S. Food and Drug Administration (FDA) has allowed multiple sclerosis patients to take home and self-administer Intranasal Foralumab, a groundbreaking treatment developed by Tiziana Life Sciences. Delivery Device Training materials have been developed and refined in collaboration with the FDA, and patients will be trained in the use of the nasal device in accordance with these materials.

Intranasal Foralumab, a novel biologic therapy, has demonstrated remarkable potential in the management of multiple sclerosis. The FDA's decision to allow patients to self-administer this treatment at home marks a significant advancement in the accessibility and convenience of care for those living with this challenging condition.

"Traditionally, MS patients have had to visit healthcare facilities for treatment, which could be inconvenient and burdensome. The FDA's approval for home dosing of Foralumab will transform the way patients manage their condition, offering them greater control over their treatment schedules and the convenience of receiving care in their familiar environment" commented Gabriele Cerrone, Chairman, acting CEO and founder of Tiziana Life Sciences on this landmark decision, saying, "We are elated with the FDA's allowance for home dosing of Intranasal Foralumab. This step significantly aligns with our mission to make innovative therapies more accessible to patients and ultimately improve their quality of life. We believe that this treatment approach will revolutionize the way multiple sclerosis patients manage their condition."

Dr. William A. Clementi, Chief Development Officer of Tiziana commented "Since the beginning of the na-SPMS EA program, patients have been going to the MS clinic at Mass General Brigham to receive their 3-times a week dosing. Now, these patients will only need to go to the clinic once every 3 weeks. This dosing and medical evaluation schedule will also be mirrored in our Phase 2a double-blind study, which is due to start in November."

"Frequent visits to the clinic for dosing is very difficult for my patients with MS," noted Dr. Tanuja Chitnis, M.D., Principal Investigator and Professor of Neurology at Harvard Medical School (HMS) and senior neurologist at Brigham and Women's Hospital, a founding member of Mass General Brigham Healthcare System. "The ability for patients to dose themselves at home is truly welcome."

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.

For further inquiries:

Tiziana Life Sciences Ltd

Paul Spencer, Business Development and Investor Relations
+44 (0) 207 495 2379
email: info@tizianalifesciences.com

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

Investors:
Irina Koffler
LifeSci Advisors, LLC
+1 646 970 4681
ikoffler@lifesciadvisors.com