



# Tiziana Announces Positive Data on Intranasal Anti-CD3 Monoclonal Antibody in Intracerebral Hemorrhage

- **Tiziana planning to advance foralumab, the only fully human anti-CD3 monoclonal antibody, into human testing for hemorrhagic stroke**
- **Data shows behavioral outcomes improvement at one month in model of intracerebral hemorrhage (hemorrhagic stroke)**
- **Modulation of neuroinflammation by inducing FoxP3+ Tregs appears to have beneficial effect in intracerebral hemorrhage**

NEW YORK, April 04, 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 pre-clinical data on the effects of intranasal anti-CD3 monoclonal antibody in a model of intracerebral hemorrhage (hemorrhagic stroke) demonstrating a behavioral outcome improvement at one month.

“Less than 10% of people who have hemorrhagic stroke completely recover, and most are left with a disability that could include lasting effects on their speech and physical function. Intranasal anti-CD3 monoclonal antibody showed improved motor and cognitive outcomes at one-month post-intracerebral hemorrhage which is very exciting.” commented Gabriele Cerrone, Executive Chairman and interim Chief Executive Officer of Tiziana. “We are actively exploring the clinical development pathway in intracerebral hemorrhage using intranasal foralumab, the first-ever fully human anti-CD3 monoclonal antibody in patients suffering from a hemorrhagic stroke. This new exciting finding further validates our decision to focus on the clinical development of our lead asset, intranasal foralumab. This potential immunomodulatory therapy represents a novel avenue for treatment of inflammatory diseases<sup>1</sup>”

## **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.<sup>1</sup>

### **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, oral and inhalation approaches in development have 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:

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