# Tiziana Life Sciences Announces Findings from Intranasal Anti-CD3 mAb Treatment in Intracerebral Hemorrhage at the Annual American Academy of Neurology Conference

- There are no effective treatments for intracerebral hemorrhage (ICH), which has a 30% to 40% mortality rate
- Intranasal anti-CD3 mAb treatment showed a reduction in Intracerebral Hemorrhage injury severity
- Intranasal foralumab could represent a novel therapeutic approach for treating ICH and potentially other types of acute brain injury

NEW YORK, April 27, 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 broad-based findings on the utility of nasal anti-CD3 mAb in the treatment of intracerebral hemorrhage (ICH). The data using a mouse model of collagenase-induced ICH was presented at the Annual American Academy of Neurology conference. The full presentation can be viewed at https://www.aan.com/MSA/Public/Events/AbstractDetails/52974 until May 14, 2023.

Howard L. Weiner, M.D., Chairman of Tiziana's Scientific Advisory Board and Co-Director of the Ann Romney Center for Neurologic Diseases at Brigham and Women's Hospital, a founding member of Mass General Brigham Healthcare System, stated, "Intracerebral hemorrhages are the deadliest form of acute stroke with early mortality ranging from 30% to 40%. It has been well demonstrated that microglial activation and edema play a critical role in the morbidity and mortality of this devastating event."

Saef Izzy, M.D., MBCHB., Neurocritical Care faculty at Brigham and Women's Hospital and Assistant Professor of Neurology at Harvard Medical School and presenter of the study at AAN, commented, "Currently, there are no effective interventions for ICH. Our research studied the effect of an intranasal anti-CD3 antibody in a mouse model of induced ICH. I believe that intranasal anti-CD3 represents a novel therapeutic approach for treating ICH as well as potentially other types of acute brain injury."

Specifically, the study demonstrated that intranasal anti-CD3 antibody:[1]

- Reduced ICH injury severity
- Improved motor coordination recovery
- Improved memory retention and functional recovery
- Accelerated hematoma resolution at 7 days after ICH
- Reduced neuronal cell death at 7 days after ICH
- Reduced BBB leakage at 3 days after ICH
- Reduced microgliosis at 7 days after ICH
- Reduced astrocytosis at 7 days after ICH
- Increased CD4+FoxP3+ and FoxP3+ IL10+ dependent Tregs at the site of hematoma at 7 days after ICH
- Increased anti-inflammatory and reduced pro-inflammatory cytokines at the site of hematoma at 7 days after ICH
- Upregulated microglial phagocytic transcriptomic profile at 7 days after ICH
- Modulated microglial and astrocyte transcriptomic inflammatory profile after ICH

“The comprehensive and consistent findings of Dr. Izzy’s research strongly supports the promising role of intranasal foralumab, the only fully human anti-CD3 monoclonal antibody (mAb), and its potential for broad applications in neuroinflammation, including the treatment of acute ICH,” said Gabriele Cerrone, Executive Chairman, Founder, and interim Chief Executive Officer of Tiziana. “These exciting findings may allow Tiziana to explore additional intranasal foralumab neuroinflammatory indications to help patients with unmet needs and create further shareholder value”.

## 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.[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,

[1] https://www.aan.com/MSA/Public/Events/AbstractDetails/52974

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

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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