



Tiziana Life Sciences Initiates Program to Develop Intranasal Foralumab in Type 1 Diabetes

- **CD3 antibody has emerged as an established and attractive target for Type 1 diabetes after the \$2.9 billion acquisition of Provention Bio by Sanofi**
- **Mechanism of Action of Tiziana's first-in-class, only fully human CD3 antibody, intranasal foralumab, makes it an ideal candidate for Type 1 diabetes**
- **Tiziana initiates program to study both the treatment and the delay of type 1 diabetes using its convenient self-administered intranasal foralumab**

NEW YORK, April 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, today announced that it is initiating a program to develop intranasal foralumab for the treatment or prevention of Type 1 Diabetes.

"With the FDA approval of the humanized anti-CD3 mAb TZIELD™ (teplizumab-mzvw injection) and then its subsequent announced acquisition of Provention Bio (Nasdaq: [PRVB](#)) by Sanofi (Nasdaq: [SNY](#)) for \$2.9 billion¹, CD3 has emerged as an established and attractive target for Type 1 Diabetes," commented Gabriele Cerrone, Executive Chairman, Founder and interim Chief Executive Officer of Tiziana. "We believed that having a fully human CD3 antibody may offer benefits to patients across many different chronic disease indications."

"The potential of not requiring an injection or infusion and having a take-home self-administered nasally delivered therapy would offer additional benefit and convenience to sufferers of Type 1 Diabetes", stated Matthew W. Davis, M.D., RPh, Chief Medical Officer of Tiziana. "Although given intranasal, our fully human anti-CD3 mAb foralumab has shown to release anti-inflammatory T regulatory cells throughout the body while returning pro-inflammatory effector T cells to their naïve state.² We are actively discussing various study designs with our Key Opinion Leaders as well as with an internationally known network of dedicated diabetes physicians. I believe that the data published in PNAS² shows that the novel immunomodulatory effects of our intranasal

¹ <https://www.sanofi.com/en/media-room/press-releases/2023/2023-03-13-06-00-00-2625367>

² <https://www.pnas.org/doi/10.1073/pnas.2220272120>

fully human anti-CD3 mAb foralumab may have an important role in the diabetes market.”

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, 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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