Tiziana Life Sciences Files New Patent Application for Combination Therapy of anti-CD3 (Foralumab) with GLP-1 Receptor Agonist for Additional Reduction of Obesity-Associated Inflammation

NEW YORK, January 5, 2024 -- Tiziana Life Sciences Ltd. (Nasdaq: TLSA) ("Tiziana" or the "Company"), a biotechnology company developing breakthrough immunomodulation therapies, today announced filing of a new patent application relating to composition and methods for combining GLP-1ra and foralumab, a fully human anti-CD3 antibody, to achieve further reductions in systemic and vascular inflammation associated with Type 2 Diabetes (T2D) and also in a separate population of patients with non T2D obesity.

Effectiveness of GLP-1ra non T2D obesity was recently shown in the >17,600 patient SELECT trial by Novo Nordisk (NYSE: NVO) (N Engl J Med 2023; 389:2221-2232(NCT03574597). SELECT showed a 20% reduction of major adverse cardiovascular events (MACE) such as heart attack, stroke, and peripheral vascular disease, with semaglutide. The risk of adverse cardiovascular events could be reduced further by the combination of intranasal foralumab and a GLP-1ra. The patent application describes the potential for foralumab to provide additional risk reduction for heart attack, stroke, and peripheral vascular disease. Foralumab given with GLP-1ra may contribute importantly to further risk reduction in this at-risk patient population.

"The GLP-1ra's have revolutionized the treatment of obesity and type 2 diabetes. Obesity and type 2 diabetes are associated with inflammation in the liver, adipose and vascular tissue. This inflammation contributes to the pathogenesis of stroke," commented Howard L. Weiner M.D. from Brigham and Women's Hospital, a founding member of Mass General Brigham Healthcare System and Professor of Neurology. "Although effective, GLP-1ra's do not completely mitigate the disease process and are associated with various side effects. Intranasal foralumab, a fully human anti-CD3, has shown efficacy in attenuating inflammation in humans with multiple sclerosis and COVID. Because intranasal foralumab induces regulatory T cells in a physiologic fashion, foralumab has novel anti-inflammatory properties that make it applicable to multiple disease conditions. Furthermore, it has had minimal side effects in both human and animal studies. We have now discovered intranasal anti-CD3's positive effect in models of diet-induced obesity related to mitigating its complications. Intranasal anti-CD3 therapy also dramatically decreases inflammation and metabolic changes. Thus,

we believe it has the potential to be an ideal therapy to be given in combination with the class of GLP-1ra approved drugs."

Gabriele Cerrone, Chairman, acting CEO and founder of Tiziana Life Sciences said, "I believe that our commitment to improving patient outcomes by using anti-CD3, or foralumab, in risk mitigation for MACE could be another exciting indication for foralumab. We hope our efforts will give a new therapeutic option to patients afflicted with Type 2 Diabetes and non T2D obesity that are receiving GLP-1 receptor antagonists. We believe the risk reduction could be substantial with combination therapy."

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 dosed its first patient in December 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.

References:

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

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

Forward-Looking Statements

Certain statements made in this announcement are forward-looking statements. These forward-looking statements are not historical facts but rather are based on the Company's current expectations, estimates, and projections about its industry, its beliefs, and assumptions. Words such as 'anticipates,' 'expects,' 'intends,' 'plans,'

'believes,' 'seeks,' 'estimates,' and similar expressions are intended to identify forward-looking statements. These statements are not guarantees of future performance and are subject to known and unknown risks, uncertainties, and other factors, some of which are beyond the Company's control, are difficult to predict, and could cause actual results to differ materially from those expressed or forecasted in the forward-looking statements. The Company cautions security holders and prospective security holders not to place undue reliance on these forward-looking statements, which reflect the view of the Company only as of the date of this announcement. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the uncertainties related to market conditions and other factors described more fully in the section entitled 'Risk Factors' in Tiziana's Annual Report on Form 20-F for the year ended December 31, 2022, and other periodic reports filed with the Securities and Exchange Commission.The forward-looking statements made in this announcement relate only to events as of the date on which the statements are made. The Company will not undertake any obligation to release publicly any revisions or updates to these forward-looking statements to reflect events, circumstances, or unanticipated events occurring after the date of this announcement except as required by law or by any appropriate regulatory authority.

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