



# Tiziana Life Sci PLC - Submission of Patent Application

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Tiziana Life Sciences PLC

16 July 2020

## **Tiziana Life Sciences plc**

("Tiziana" or the "Company")

### **Tiziana Announces Submission of Patent Application on Use of Foralumab, the Only Fully Human Anti-CD3 Monoclonal Antibody, to Enhance Success of CAR-T Therapy**

New York/London, July 16, 2020 - Tiziana Life Sciences plc (Nasdaq: TLSA / AIM: TILS) ("Tiziana" or the "Company"), a biotechnology company focused on innovative therapeutics for oncology, inflammation and infectious diseases, is pleased to announce that it has submitted a patent application on potential use of Foralumab, a fully human anti-CD3 monoclonal antibody (mAb), to improve success of CAR-T therapy for cancer and other human diseases. The patent application conveys inventions related to improving CAR-T expansion and/or survival using anti-CD-3 mAbs administered either alone or in combination with other co-stimulatory molecules, such as an anti-IL-6 receptor monoclonal antibody, an anti-CD28 monoclonal antibody or specific inhibitors of signaling pathways of phosphatidylinositol 3-kinase (PI3K), protein kinase B (AKT), or mammalian target of rapamycin (mTOR).

- *Foralumab treatment could potentially enhance expansion and survival of chimeric antigen receptor T cells (CAR-T) therapy for cancers and other human diseases*
- *Foralumab may be co-administered either alone or in combination with other drugs to improve success of CAR-T therapy*

"The CAR-T is one of the most promising therapies utilizing T cells from your own immune system, which are genetically engineered and supercharged to hunt down and destroy cancer cells. In this context, we are developing oral and nasal administrations of Foralumab for the treatment of Crohn's Disease and

progressive multiple sclerosis, respectively. The common underlying approaches in these programs are to strengthen your own body defenses to fight against these diseases. Being a fully human anti-CD3 mAb, Foralumab is most suitable for CAR-T therapy as it does not produce an immune response unlike other humanized anti-CD3 mAbs" commented Dr. Shailubhai, CEO and CSO of Tiziana Lifesciences.

Typically, CAR-T cell therapies are created using a patients' own T cells that have been engineered to express a chimeric antigen receptor (CAR) to reprogram the T cells to kill cancer cells. The CAR combines the specificity of a mAb with the cytotoxic and memory functions of T cells. CAR-T cell therapy has shown tremendous promise in the treatment of a variety of hematological and solid cancers, and potentially for patients with autoimmune diseases. Despite encouraging clinical success, relapse rates following CAR-T therapy are high, limiting the utility of this promising cancer therapy. An improved CAR-T therapy can be achieved through more efficient production processes by optimizing the *ex vivo* expansion conditions and/or providing concomitant therapies utilizing anti-CD3 mAbs, either alone or in combination with other co-stimulatory molecules such as an anti-IL-6 receptor mAbs, an anti-CD28 mAbs or specific inhibitors of signaling pathways of phosphatidylinositol 3-kinase (PI3K), protein kinase B (AKT), or mammalian target of rapamycin (mTOR).

**This announcement contains inside information for the purposes of Article 7 of the Market Abuse Regulation (EU) 596/2014 ("MAR"), encompassing information relating to the Placing as described above, and is disclosed in accordance with the Company's obligations under Article 17 of MAR.**

The person who arranged for the release of this announcement on behalf of the Company was Dr Kunwar Shailubhai, Chief Executive Officer and Chief Scientific Officer of the Company.

#### **About Foralumab**

Foralumab (formerly NI-0401), the only entirely human anti-CD3 mAb, shows reduced release of cytokines after IV administration in patients with Crohn's disease with decreases in the classic side effects of cytokine release syndrome (CRS) and improves the overall safety profile of Foralumab. In a humanized mouse model (NOD/SCID IL2 $\gamma$ c-/-), it was shown that while targeting the T cell receptor, orally administered Foralumab modulates immune responses of the T cells, enhances regulatory T-cells (Tregs) and thus provides therapeutic benefit in treating inflammatory and autoimmune diseases without the occurrence of potential adverse events usually associated with parenteral mAb therapy (Ogura M. et al., 2017). Based on animal studies, the nasal and oral administration of Foralumab offers the potential for the immunotherapy of autoimmune and inflammatory diseases in a safe manner by the induction of Tregs.

#### **About Tiziana Life Sciences**

Tiziana Life Sciences plc is a dual listed (NASDAQ: TLSA & UK AIMS: TILS) biotechnology company that focuses on the discovery and development of novel molecules to treat human diseases in oncology, inflammation and infectious diseases. In addition to milciclib, the Company will be shortly initiating phase 2 studies with orally administered foralumab for Crohn's Disease and nasally administered foralumab for progressive multiple sclerosis. Foralumab is the only fully human anti-CD3 monoclonal antibody (mAb) in clinical development in the world. This phase II compound has potential application in a wide range of autoimmune and inflammatory

diseases, such as Crohn's Disease, multiple sclerosis, type-1 diabetes (T1D), inflammatory bowel disease (IBD), psoriasis and rheumatoid arthritis, where modulation of a T-cell response is desirable. The company is accelerating development of anti-Interleukin 6 receptor (IL6R) mAb, a fully human monoclonal antibody for treatment of IL6-induced inflammation, especially for treatment of COVID-19 patients.

### **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. 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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