

Tiziana Life Sciences plc To Expedite Development of its Fully Human Anti-Interleukin-6-Receptor Monoclonal Antibody, a Potential Treatment of Certain Patients Infected with Coronavirus COVID-19

Wednesday 11 March, 2020

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Tiziana Life Sciences plc

("Tiziana" or the "Company")

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New York/London, March 11, 2020 – Tiziana Life Sciences plc (Nasdaq: TLSA; AIM: TILS) ("Tiziana" or the "Company"), a biotechnology company focused on innovative therapeutics for inflammatory and autoimmune diseases, announced today that it is expediting development of TZLS-501, a novel, fully human anti-interleukin-6 receptor (anti-IL6R) monoclonal antibody (mAb) for treatment of patients infected with coronavirus COVID-19 (SARS-CoV-2). Tiziana plans to administer TZLS-501 using a proprietary formulation technology. The Company entered into a world-wide license for composition-of-matter of TZLS-501, a fully human mAb targeting IL-6R, with Novimmune, SA, a Swiss biotechnology company in 2017.

Certain patients infected with coronavirus COVID-19 may develop an uncontrolled immune response ("cytokine storm") resulting in severe damage to lung tissue which could lead to respiratory failure (see Note 1, below). Early clinical studies conducted by doctors in China suggest that anti-IL6R mAbs may be used in clinical practice for treatment of COVID-19. Consequently, China's National Health Commission has recommended the use of Roche's blockbuster drug, Actemra® for treatment of patients infected with COVID-19, with serious lung damage and elevated IL-6 levels. Actemra was first approved by the FDA in 2010 for rheumatoid arthritis. Besides Actemra®, Sanofi and Regeneron are currently exploring Kevzara®, an FDA-approved anti-IL-6 receptor therapy for rheumatoid arthritis, for treatment of severe COVID-19.

Tiziana's anti-IL-6R mAb binds to both the membrane-bound and soluble forms of IL-6R and rapidly depletes circulating levels of IL-6 in the blood (see Note 2, below). An excessive production of IL-6 is regarded as a key driver of chronic inflammation and is believed to be associated with severe lung damage observed with COVID-19 infections and acute respiratory illness. A recent Chinese study also reported that COVID-19 infection caused clusters of severe respiratory illness such as severe acute respiratory distress syndrome (ARDS) (see Note 3, below).

"We believe that the features of TZLS-501 consisting of its dual mechanism of action to inhibit signaling by the membrane-bound and soluble IL-6 receptors along with rapid depletion of circulating IL-6 cytokine, a major cause of lung damage, provides TZLS-501 with distinct advantages for treatment of COVID-19 over other anti-IL-6R mAbs such as Actemra® and Kevzara® for treatment of COVID-19. The recent decision by researchers in China to add Actemra® to treatment guidelines for coronavirus patients with serious lung damage confirms the utility of anti-IL6R mAb. We are excited to move forward with our clinical development plan to expedite evaluation in patients as soon as possible", said Dr. Kunwar Shailubhai, CEO & CSO of Tiziana Life Sciences.

Notes

Reference is made above to the following third-party publications:

1. **Chaolin Huang, et al.**, Clinical features of patients infected with 2019 novel coronavirus in Wuhan, China. The Lancet, volume 395, pages 497-506. 2020. Published online January 24, 2020.
2. **Chan, Jasper Fuk-woo et. al.**, A familiar cluster of pneumonia associated with the 2019 novel coronavirus indicating person-to-person transmission: a study of a family cluster. The Lancet,

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Coronavirus :: Anti-IL-6r :: COVID-19 Treatment :: COVID-19 ::

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volume 395, pages 514-523. 2020. Published online January 24, 2020.

3. Lacroix, M. et al., Novel Insights into Interleukin 6 (IL-6) Cis- and Trans-signaling Pathways by Differentially Manipulating the Assembly of the IL-6 Signaling Complex. J Biol Chem. 2015 Nov 6; 290(45): 26943–26953.

The person who arranged for the release of this announcement was Dr. Kunwar Shailubhai, CEO & CSO of Tiziana Life Sciences.

About TZLS-501

TZLS-501, a fully human mAb, was acquired from Novimmune, SA, a Swiss biotechnology company, in 2017. The cytokine, IL-6, a major determinant in the priming of pathogenic T cells to produce an inflammatory response, binds to its receptor subunit IL-6R α on the cell membrane. The receptor IL-6R α can be shed in soluble form, sIL6R α , which binds to circulating IL-6 cytokine in the blood. The downstream signaling from this complex mediates pro-inflammatory effects underlying inflammatory diseases such as rheumatoid arthritis (RA) and acute respiratory distress syndrome (ARDS). The Company believes that the features of TZLS-501 consisting of its dual mechanism of action to inhibit signaling by the membrane-bound and soluble IL-6 receptor and the rapid depletion of circulating IL-6 cytokines, a major cause of lung damage, provides TZLS-501 with distinct advantages for treatment of COVID-19.

About Tiziana Life Sciences

Tiziana Life Sciences plc is a UK biotechnology company that focuses on the discovery and development of novel molecules to treat human disease in oncology and immunology. In addition to Milciclib, the Company is also developing Foralumab for liver diseases. Foralumab is the only fully human anti-CD3 monoclonal antibody in clinical development in the world. This monoclonal antibody has potential application in a wide range of autoimmune and inflammatory diseases, such as nonalcoholic steatohepatitis (“NASH”), ulcerative colitis, multiple sclerosis, type-1 diabetes (“T1D”), Crohn’s disease, psoriasis and rheumatoid arthritis, where modulation of a T-cell response is desirable.

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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