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SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549
FORM 6-K
REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16 UNDER THE SECURITIES EXCHANGE ACT OF 1934
June 2019
Commission File Number: 0001723069
Tiziana Life Sciences plc (Exact Name of Registrant as Specified in Its Charter)
3 rd Floor, 11-12 St James's Square London SW1Y 4LB United Kingdom (Address of registrant's principal executive office)
Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.
Form 20-F ⊠ Form 40-F □
Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): \Box
Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): \Box

INFORMATION CONTAINED IN THIS REPORT ON FORM 6-K

On June 24, 2019, Tiziana Life Sciences plc (the "Company") issued a regulatory news service announcement, announcing the publication of an article reporting Clinical Activity of Orally Administered OKT3, a Mouse Anti-CD3 Monoclonal Antibody, in Moderate to Severe Ulcerative Colitis Patients, Supports Tiziana's Oral Monoclonal Antibody Platform (the "RNS Announcement").

The RNS Announcement is furnished herewith as Exhibit 99.1 to this Report on Form 6-K. The information in the attached Exhibit 99.1 is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, or otherwise subject to the liabilities of that Section, nor shall it be deemed incorporated by reference in any filing made by the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, except as otherwise set forth herein or as shall be expressly set forth by specific reference in such a filing.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: June 24, 2019

TIZIANA LIFE SCIENCES PLC

/s/ Kunwar Shailubhai Name: Kunwar Shailubhai Title: Chief Executive Officer

EXHIBIT INDEX

Exhibit No.	Description
99.1	Regulatory News Service Announcement, dated June 24, 2019
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Tiziana Life Sciences plc

Newly Published Article Reporting Clinical Activity of Orally Administered OKT3, a Mouse Anti-CD3 Monoclonal Antibody, in Moderate to Severe Ulcerative Colitis Patients, Supports Tiziana's Oral Monoclonal Antibody Platform

Third party research conducted by leading U.S. institutions to be published in a peer reviewed journal Crohn's & Colitis 360 shows orally administered anti-CD3 resulted in anti-inflammatory gene expression with no serious treatment related adverse events up to a dose of 1 mg of OKT3

Tiziana's platform oral monoclonal antibody (mAb) technology applicable to mAb's on the market today which are currently available only through IV, addressing an enourmous market potential.

Tiziana's Foralumab is the first fully human anti-CD3 mAb which has not shown anti-drug antibody (immune reaction) in humans

New York/London, 24 June 2019 - Tiziana Life Sciences plc (Nasdaq: TLSA / AIM: TILS) ("Tiziana" or the "Company"), a biotechnology company focusing on the discovery and development of innovative therapeutics for inflammation and oncology indications, notes the advance publication of a scientific article by third party researchers in the peer reviewed journal *Crohn's & Colitis 360** titled, "Immunologic alterations associated with oral delivery of anti-CD3 (OKT3) monoclonal antibodies in patients with moderate-to-severe ulcerative colitis"(1) The published study was conducted at some of the leading medical research institutions in the world, including Harvard Medical School, Massachusetts General Hospital, and the Ann Romney Center for Neurologic Diseases at Brigham & Women's Hospital. These independent findings suggest potential clinical activity and support the safety of monoclonal antibodies (mAb's) when administered orally.

Tiziana's Foralumab, the only fully human anti-CD3 mAb, exhibits potency and functionality similar to OKT3, which is a mouse anti-CD3 (2). Therapeutic use of intravenously administered OKT3 and other humanized anti-CD3 mAbs is limited due to significant adverse reactions, including life threatening cytokine release syndrome. The Company is pioneering oral delivery of mAb's for the treatment of autoimmune and inflammatory diseases that is applicable to the \$100 billion market of mAb's that are currently only available through IV delivery.

"The safe and effective oral delivery of mAb's has the potential to transform the use of biologic medications. While the scientific community has long recognized oral delivery of proteins and peptides as a challenge, we believe our propeitary platform technology is a breakthrough in oral delivery of mAb's," stated Kunwar Shailubhai, CEO & CSO of Tiziana. "We are pleased to see that some of the top researchers in the world are now validating the concept of oral administration of mAbs. Oral administration with Foralumab may have the potential to deliver superior safety and efficacy results in autoimmune and inflammatory diseases such as NASH and Crohn's disease."

Foralumab is currently in a Phase 1 trial at the Harvard Medical School in healthy volunteers to study safety, tolerability and biomarkers of neurodegenerative disease through nasal delivery. An upcoming Phase 1 trial will evaluate oral Foralumab's safety, tolerability and biomarkers in Crohn's disease and NASH. A Phase 2 trial in Crohn's and NASH is expected to commence next year.

The aim of this pilot study was to determine the immunologic effects and safety of orally delivered anti-CD3 antibody in patients with moderate-to-severe ulcerative colitis (UC). (1)

The primary endpoints were changes in immunologic parameters and evaluation for safety. Six subjects received oral OKT3. The biologic effects of oral anti-CD3 included significantly increased proliferation in response to anti-CD3 and anti-inflammatory gene expression profile in peripheral blood mononuclear cells. No serious treatment-related adverse events occurred.

Cited References:

(1).Boden, E. K., Canavan, J. B., Moran, C. J., McCann, K., Dunn, W. A., Farraye, F. A., Ananthakrishnan, A. N., Yajnik, V., Gandhi, R., Nguyen, D. D., Bhan, A. K., Weiner, H. L., Korzenik, J. R., Snapper, S. B. *Immunologic alterations associated with oral delivery of anti-CD3 (OKT3) monoclonal antibodies in patients with moderate-to-severe ulcerative colitis.* Crohn's & Colitis 360 (2019). 183: 240-246.

(2).Ogura M¹, Deng S¹, Preston-Hurlburt P¹, Ogura H¹, Shailubhai K², Kuhn C³, Weiner HL³, Herold KC⁴. Oral treatment with foralumab, a fully human anti-CD3 monoclonal antibody, prevents skin xenograft rejection in humanized mice. Clin Immunol. 2017 Oct;183:240-246. doi: 10.1016/j.clim.2017.07.005. Epub 2017 Jul 21.

About Foralumab

Foralumab (formerly NI-0401), the only entirely human anti-CD3 mAb, has shown 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 enhances the overall safety profile of Foralumab. In a humanized mouse model, it was shown that while targeting the T cell receptor, orally administered Foralumab modulates immune responses of the T cells, enhances Tregs and thus has the potential to provide 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 OKT3

Muromonab-CD3 (Orthoclone OKT3) is a murine anti-human CD3 monoclonal antibody. OKT3 was developed by Johnson and Johnson and it was the first monoclonal antibody approved by the FDA in 1985 to be administered to humans via the intravenous route for the trearment of acute, glucocorticoid-resistant rejection of allogenic renal, heart and liver transplants. However, manufacture of OKT3 was voluntarily withdrawn from the market.

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 Phase 2 compound has potential application in a wide range of autoimmune and inflammatory diseases, such as nonalcoholic steatohepatitis (NASH), primary biliary cholangitis (PBS), ulcerative colitis, multiple sclerosis, type-1 diabetes (T1D), inflammatory bowel disease (IBD), psoriasis and rheumatoid arthritis, where modulation of a T-cell response is desirable.

For further enquiries:

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