
**UNITED STATES
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**

December 2019

Commission File Number: 0001723069

Tiziana Life Sciences plc
(Exact Name of Registrant as Specified in Its Charter)

**3rd 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):

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):

INFORMATION CONTAINED IN THIS REPORT ON FORM 6-K

On December 4, 2019, Tiziana Life Sciences plc (the “Company”) issued a regulatory news service announcement in the United Kingdom Reporting the Initiation of a Phase 1 Clinical Trial with Orally Administered Foralumab, a Fully Human anti-CD3 monoclonal antibody, in Healthy Volunteers (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.

TIZIANA LIFE SCIENCES PLC

Date: December 4, 2019

By: /s/ Kunwar Shailubhai

Name: Kunwar Shailubhai

Title: Chief Executive Officer

EXHIBIT INDEX

Exhibit No.	Description
99.1	Regulatory News Service Announcement, dated December 4, 2019

Tiziana Life Sciences plc
(“Tiziana” or the “Company”)

Tiziana Announces Initiation of a Phase 1 Clinical Trial with Orally Administered Foralumab, a Fully Human anti-CD3 monoclonal antibody, in Healthy Volunteers

This announcement contains inside information for the purposes of Article 7 of EU Regulation 596/2014.

London/New York, 4 December 2019 – Tiziana Life Sciences plc (Nasdaq: TLSA / AIM: TILS), a clinical-stage biotechnology company focused on developing innovative therapeutics for inflammatory diseases and cancers, is pleased to announce initiation of a Phase I clinical trial in healthy volunteers with a proprietary oral formulation of Foralumab encapsulated in enteric-coated capsules. The primary objective of this single ascending dose (SAD) phase 1 study, being led by Dr. Tanuja Chitnis at the Brigham and Women’s Hospital, Harvard Medical School, Boston, MA USA, is to determine safety and tolerability of orally administered Foralumab. The clinical protocol also includes evaluation of pharmacokinetics to determine if there is any systemic absorption of Foralumab following oral administration.

“Oral administration of Foralumab in enteric-coated capsules is a novel approach to upregulate T regulatory cells (Tregs) that have the capability to cross-through blood brain barrier and provide clinical benefits. Successful demonstration of safety in this study will facilitate immediate evaluation of orally administered Foralumab in a phase 2 clinical study in patients with progressive multiple sclerosis, a neurodegenerative disease for which there are limited treatment options”, said Dr. Howard Weiner

“We are excited to initiate this trial because this is the first-ever clinical study with orally administered Foralumab in enteric-coated capsules. The oral route of administration is expected to minimize toxicities associated with intravenous administration of anti-CD3 mAbs and it may also improve the clinical outcome through activation of gut mucosal immunity. Our proprietary oral formulation technology has the potential to be useful for treatment of neurodegenerative and gastrointestinal diseases,” commented Kunwar Shailubhai, CEO and CSO of Tiziana.

About Dr. Howard Weiner

Dr. Howard L. Weiner is the Robert L. Kroc Professor of Neurology at the Harvard Medical School, Director and Founder of the Partners Multiple Sclerosis (MS) Center and Co-Director of the Ann Romney Center for Neurologic Diseases at Brigham & Women’s Hospital in Boston. He has pioneered immunotherapy in MS and has investigated immune mechanisms in nervous system diseases including MS, Alzheimer’s disease, amyotrophic lateral sclerosis, stroke and brain tumors. He has also pioneered the investigation of the mucosal immune system for the treatment of autoimmune and other diseases and the use of anti-CD3 to induce Tregs for the treatment of these diseases.

About Dr. Tanuja Chitnis

Dr. Tanuja Chitnis is a Professor of Neurology at the Harvard Medical School, and Director of the Translational Neuroimmunology Research Center at Brigham & Women’s Hospital in Boston. She has led studies including the testing of nasal Foralumab in healthy volunteers and a study of fingolimod in pediatric MS that led to FDA approval.

About Harvard Medical Centre

Brigham and Women's Hospital (BWH) is located adjacent to Harvard Medical School, of which it is the second largest teaching affiliate. It is the largest hospital of the Longwood Medical and Academic Area in Boston, Massachusetts, USA. With Massachusetts General Hospital, it is one of the two founding members of Partners HealthCare, the largest healthcare provider in Massachusetts. BWH conducts the second largest hospital-based research program in the world, with an annual research budget of more than \$630 million. Pioneering milestones include the world's first successful heart valve operation and the world's first solid organ transplant.

About Neurodegenerative diseases

Neurodegenerative diseases include Alzheimer's, multiple sclerosis, Huntington's disease, Parkinson's disease, ALS and others. Among these, Alzheimer's is the most prevalent disease. In 2013 the global market for AD was 4.9 billion and expected to rise to 13 billion by the end of 2023. Current treatments for neurodegenerative diseases are mainly symptomatic, but new disease-modifying drugs to slow or stop the progression of the disease are now emerging. Three AChE inhibitors are currently in use for AD, i.e. donepezil (Aricept), rivastigmine (Exelon) and galantamine (Reminyl) and cladribine (Mavenclad) for MS. It is recognized that inflammation plays a critical role in neurodegenerative diseases of the CNS. Immune-directed therapies for neurodegenerative diseases target immune system cells such as the T cells that cause inflammatory and autoimmune disease in MS and microglia in ALS and show promise. It has been shown in animal models of progressive MS that anti-CD3 antibody targeting T cells ameliorates disease. These effects were shown to be IL-10 dependent, mediated by regulatory T cells leading to suppression of the disease. There is great promise in ongoing studies of inflammation-targeted neuroprotective strategies, which may ultimately be used across neurodegenerative diseases.

About Tiziana Life Sciences

Tiziana 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 miliclib, the Company is also developing Foralumab for liver diseases. Foralumab is the only fully human anti-CD3 mAbs in clinical development in the world. This compound has potential application in a wide range of autoimmune and inflammatory diseases, such as Crohn's disease (CD), nonalcoholic steatohepatitis (NASH), primary biliary cholangitis (PBC), 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 more information go to <http://www.tizianalifesciences.com>

The person who arranged for the release of this announcement on behalf of the Company was Kunwar Shailubhai, CEO of Tiziana.

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