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

May 2020

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 o

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): o

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): o

INFORMATION CONTAINED IN THIS REPORT ON FORM 6-K

On May 14, 2020, Tiziana Life Sciences plc (the "Company") issued a regulatory news service announcement in the United Kingdom announcing that Tiziana Life Sciences has two abstracts published online at the American Society of Clinical Oncology (ASCO) Reporting Clinical Activity and Safety of Milciclib in Patients with Advanced Hepatocellular Carcinoma (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: May 14, 2020

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Regulatory News Service Announcement, dated May 14, 2020

Exhibit 99.1

Tiziana Life Sciences plc
("**Tiziana**" or the "**Company**")

Tiziana Life Sciences Announces Online Publication of Two Abstracts at the American Society of Clinical Oncology (ASCO) Reporting Clinical Activity and Safety of Milciclib in Patients with Advanced Hepatocellular Carcinoma

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

New York and London, May 14, 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, today announces the online publication of two abstracts on clinical studies with Milciclib, a small molecule pan-inhibitor of cyclin dependent kinases (CDKs) in the proceedings of the virtual annual meeting of American Society of Clinical Oncology 2020 (ASCO20).

The first abstract reports Phase 2a clinical data with orally administered Milciclib in sorafenib-resistant hepatocellular carcinoma (HCC) patients, for which it met the primary endpoint that oral treatment with Milciclib was well tolerated with manageable toxicities and no recorded drug-related deaths. The second abstract reports clinical data from an ongoing investigator-originated trial with combination of orally administered Milciclib and Regorafenib in liver transplant patients with recurrent HCC. Thus far, the study has shown mean AFP levels (a common tumor biomarker) reduced by a mean of approximately 20% within one month of treatment.

MAJOR HIGHLIGHTS

Abstract #298561: *Phase 2a Safety and Efficacy of Milciclib, a Pan-Cyclin Dependent Kinase Inhibitor, in Unresectable, Sorafenib-Refractory or -Intolerant Hepatocellular Carcinoma Patients. First Author: Erica Villa, MD., et al.*

- Phase 2a multi-centered clinical evaluation of Milciclib (100 mg once daily; 4 days on/3 days off for 4 weeks; defining each cycle) for 6-month in 28 evaluable out of 31 enrolled patients in Italy, Greece and Israel.

- The trial successfully met the primary endpoint that oral treatment with Milciclib was well tolerated with manageable toxicities and no recorded drug related deaths.

- The secondary endpoints for clinical activity assessment were based on the independent radiological review using the modified Response Evaluation Criteria in Solid Tumors (mRECIST)

- Positive demonstrated clinical activity included:

    1. 50% (14 out of 28) evaluable patients completed 6-month duration of the trial.

    2. 64% (9 out of 14) patients requested and were approved by their respective ethical committees to continue the treatment

    3. Both median time to progression (TTP) and progression free survival (PFS) were 5.9 months (95% Confidence Interval ("CI") 1.5-6.7 months) out of the 6-months duration of the trial.

4. Approximately 57% of evaluable patients showed 'Stable Disease' (SD; met at least once in an 8-week interval) and 3.6% patients showed 'Partial Response' (PR).

5. Approximately 61% of patients showed 'Clinical Benefit Rate' defined as CBR=CR+PR+SD (with CR representing Complete Remission).

6. Five patients on compassionate use continued the treatment for a total of 9, 9, 11, 13 and 16 months, respectively. Two patients continuing the treatment have reached 16 months

“Advance cases of patients with HCC have limited therapeutic options because of the poor safety and tolerability of existing drugs. Thus, a newer drug, preferentially with a different mechanism of action, such as Milciclib is a necessary medical need,” stated Prof. Angelo Sangiovanni, M.D. principal investigator of the study and site investigator at Fondazione IRCCS Cà Granda Ospedale Maggiore Policlinico, Milan, Italy. “In this context, safety, and tolerability of oral treatment with Milciclib is remarkable. Results from the phase 2a clinical study demonstrating clinical activity in these advance cases of HCC are notable. The fact that many of the treated patients continued with the treatment, even after completing 6 months duration of the study, is particularly very impressive.”

Abstract #307309: *Safety and Clinical Activity of Combination Treatment with Regorafenib and Milciclib in Liver Transplant Patients with Hepatocellular Carcinoma Recurrence. First Author: Alessandro Pivetti. MD., et al.*

- Seven patients enrolled to date in this ongoing study
- Combination treatment of Milciclib and Regorafenib was well tolerated with manageable toxicities
- Mean AFP levels reduced by 20% within one month of treatment
- Patients treated for longer duration had 50% reduction in AFP levels
- Currently, patients enrolled in the study are in 2 to 10 months of treatment period

"Our center has been involved with clinical evaluation of several drug candidates in advanced HCC patients and both of the above-mentioned studies were conducted at our site. The oral treatment with Milciclib is not only very well tolerated but it also showed clinical activity. Most of these patients with advance cases of HCC are exhibiting stabilization of disease and have continued the treatment under compassionate use program, which in my opinion is very impressive,” added Prof. Erica Villa, M.D., site Investigator at the Policlinico di Modena, Modena, Italy. “Moreover, the positive clinical activity and impressive safety and tolerability of Milciclib in combination with Regorafenib in liver transplant patients with recurrent HCC is certainly noteworthy. Thus, clinical data from these two studies are very encouraging and warrant continued development of Milciclib, either as monotherapy or combination therapy."

About Milciclib (TZLS-201)

Milciclib (PHA-848125AC) is a small molecule inhibitor of several cyclin dependent kinases such as CDK1, CDK2, CDK4, CDK5 and CDK7. CDKs are serine threonine kinases that play crucial roles in progression of the cell cycle from G_1 to S phase. Overexpression of CDKs and other downstream signalling pathways that regulate cell cycles have been frequently found to be associated with development of resistance towards chemotherapies. In a phase I study, oral treatment with Milciclib was found to be well-tolerated and the drug showed promising clinical responses in patients with advanced solid malignancies such as in NSCLC, pancreatic and colon cancer, thymic carcinoma and thymoma.

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.

About ASCO

The American Society of Clinical Oncology (ASCO) was established in 1964 with the sole purpose of improving the care of people with cancer. Membership currently stands at 40,000 physicians and scientists. ASCO is one of the premiere organizations for the advancement of cancer treatments and the annual ASCO meeting is an important forum for discussion of new cancer therapies and treatments.

For more information go to http://www.tizianalifesciences.com

THE PERSON WHO ARRANGED FOR THE RELEASE OF THIS INFORMATION IS DR KUNWAR SHAILUBHAI, THE COMPANY'S CHIEF EXECUTIVE AND CHIEF SCIENTIFIC OFFICER.

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