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

July 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 July 22, 2019, Tiziana Life Sciences plc (the "Company") issued a regulatory news service announcement in the United Kingdom Reporting the Phase 2a Clinical Data with Milciclib Monotherapy in Sorafenib-refractory or -intolerant patients with unresectable or metastatic 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: July 22, 2019

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Regulatory News Service Announcement, dated July 22, 2019

Exhibit 99.1

THE INFORMATION CONTAINED IN THIS ANNOUNCEMENT IS DEEMED BY THE COMPANY TO CONSTITUTE INSIDE INFORMATION AS STIPULATED UNDER THE EU MARKET ABUSE REGULATION (596/2014). UPON PUBLICATION OF THE ANNOUNCEMENT VIA A REGULATORY INFORMATION SERVICE, THIS INFORMATION IS CONSIDERED TO BE IN THE PUBLIC DOMAIN.

Tiziana Life Sciences plc

(the 'Company', 'Tiziana Life Sciences' or 'Tiziana')

Tiziana Reports Phase 2a Clinical Data with Milciclib Monotherapy in Sorafenib-refractory or -intolerant patients with unresectable or metastatic Hepatocellular Carcinoma

- ***Milciclib was well tolerated and no drug related deaths were reported***
- ***28 out of 31 treated patients were evaluable, with 14 patients completing the 6-month study duration***
- ***9 patients continued treatment under compassionate use, of which 5 are currently continuing with treatment***

New York/London, 22 July 2019 - Tiziana Life Sciences plc (NASDAQ: TLSA / AIM: TILS), a biotechnology company focusing on the discovery and development of innovative therapeutics for inflammation and oncology indications, today announced preliminary topline clinical data from a Phase 2a trial of Milciclib as a monotherapy in patients with advanced hepatocellular carcinoma (HCC), the most common form of liver cancer. The primary endpoint of the study was overall safety. Under compassionate use, a few patients continued with total treatment for up to 16 months. Overall, treatment with Milciclib was well-tolerated and no drug-related deaths were recorded. Secondary endpoints of efficacy including progression-free survival (PFS) and time to progression (TTP) are currently being evaluated and will subsequently be reported.

This Phase 2a trial with Milciclib monotherapy was a multi-centered, single-arm, repeated-dose (100 mg once daily; 4 days on/3 days off every 4 weeks; defining each cycle), 6-month duration study to evaluate the safety, tolerability and anti-tumor activity of Milciclib in sorafenib-refractory or intolerant patients with unresectable or metastatic advanced HCC. This trial enrolled 31 patients in Italy, Greece, and Israel.

Among the 28 evaluable patients, 14 completed the 6-month duration study. Oral treatment with Milciclib was well-tolerated with manageable toxicities. The most frequent adverse events such as diarrhea, ascites, nausea, fatigue, asthenia, fever, ataxia, headache, and rash were manageable.

9 out of the 14 patients, after completing the 6-month trial period, requested to continue the treatment under compassionate use and were approved by their respective ethical committees. Four of the patients received Milciclib for a total of 9, 11, 13 and 16 months. The remaining 5 patients are continuing treatment with Milciclib are at 8th, 9th, 9th, 9th and 11th month currently.

Objective tumor assessments according to the modified Response Evaluation Criteria in Solid Tumors (mRECIST) guideline and the conventional RECIST 1.1 criteria are being conducted by Independent Central Review and data will be available in September 2019.

'We are very pleased with the clinical activity and tolerability of Milciclib in these advanced cases of HCC. It is an important milestone to move forward with further clinical development of Milciclib either as a single agent or in combination with other HCC drugs,' said Dr. Kunwar Shailubhai, CEO & CSO of Tiziana.

These data are consistent with the earlier reported long-term safety and clinical activity of Milciclib in thymic carcinoma, thymoma[1] and other solid cancers[2].

The global market for liver cancer drugs is estimated to reach $1.47 billion by 2022. The current standard of care drugs is not entirely satisfactory due to low response rates and severe toxicities. Importantly, patients often become resistant or unresponsive to the treatment. Milciclib works through a unique mechanism of action and the Company therefore believes it may have the potential for long-term efficacy with a good safety profile in a larger subset of patients.

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

Cited References

1. Besse, B., Garassino, M., Rajan, A., Novello, S., Mazieres, J., Weiss, G., Kocs, D., Barnett, J, Davite, C, Crivori, P and G. Giaccone. Efficacy of milcicilib (PHA-848125AC), a pan-cyclin D -dependent kinase inhibitor in tow phase II studies with Thymic carcinoma and B3 thymoma patients. (2018) J. Clin. Onc 36 (15 suppl): 8519

2. Aspeslagh, S., Shailubhai, K., Bahleda, R. et al. (2017). Phase I dose-escalation study of Milciclib in combination with gemcitabine in patients with refractory solid tumors. Cancer Chemother Pharmacol. 79:1257-1265.

Contacts:

Tiziana Life Sciences plc
+44 (0)20 7495 2379
Gabriele Cerrone, Chairman and founder

Cairn Financial Advisers LLP (Nominated adviser)
+44 (0)20 7213 0883
Liam Murray / Jo Turner

Shore Capital (Broker)
+44 (0)20 7601 6125
Andy Crossley / Antonio Bossi

Receive news and updates from Tiziana Life Sciences Plc by signing up to get email alerts straight to you on https://ir.tizianalifesciences.com

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.

About HCC

HCC is the fifth most common cancer and the third highest cause of cancer mortality worldwide. In 2007, the approval by the European Medical Agency and U.S. Food and Drug Administration of Sorafenib (Nexavar®), an inhibitor of several receptor tyrosine kinases, in HCC represented the first systemic therapy for improving outcome in patients unsuitable for loco-regional and surgical therapies and created a new standard of treatment for the disease. However, although significant in respect to placebo, the benefits of Sorafenib are modest, with a response rate less than 3%, an improvement in median survival of 2-3 months and drug-related symptoms that are not ordinary. More recently, lenvatinib (Lenvima ®), another multi-tyrosine kinase inhibitor was also approved for first line treatment of HCC. The complex multi-factorial etiology of HCC warrants a need for systemic therapies that target different signaling cascades to provide improved efficacy and safety for both naive patients presenting with unresectable, advanced stage and those who suffer recurrence after curative treatments (resection, ablation and transplantation).

About Milciclib

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 G1 to S phase. Overexpression of CDKs and other downstream signaling pathways that regulate cell cycles have been frequently associated with development of resistance towards chemotherapies. In a Phase 1 study, oral treatment with Milciclib was 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. Additionally, milciclib met its primary endpoint in two separate Phase 2 multi-center clinical trials (CDKO-125A-006: 72 patients and CDKO-125A-007: 30 patients) in thymic carcinoma and thymoma patients.

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.