
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**

April 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 April 24, 2019, Tiziana Life Sciences plc (the “Company”) issued a regulatory news service announcement, announcing Interim Clinical Data from an Ongoing Phase 2a Trial with Milciclib in Advanced Liver Cancer Patients (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: April 24, 2019

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Regulatory News Service Announcement, dated April 24, 2019

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

Tiziana Reports Encouraging Interim Clinical Data from an Ongoing Phase 2a Trial with milciclib in Advanced Liver Cancer Patients

- **80% of patients who completed treatment within the trial’s timeframe requested to continue treatment under compassionate use**
- **Independent Data Monitoring Committee finds no unexpected signs or signals of toxicity**
- **Top line data expected Q3 2019**

New York/London, 24 April 2019 - Tiziana Life Sciences plc (Nasdaq: TLISA / AIM: TILS), a biotechnology company focusing on the discovery and development of innovative therapeutics for inflammation and oncology indications, today announced results from the interim safety review conducted by the Independent Data Monitoring Committee (IDMC) on March 21, 2019. The IDMC reviewed safety data from patients as of February 26, 2019, and concluded that the administration of milciclib to patients with advanced hepatocellular carcinoma (HCC) was not associated with unexpected signs or signals of toxicity. Additionally, a number of patients are continuing with treatment under compassionate use. Topline data from this multi-center trial is expected to be available by the end of Q3 2019.

Tiziana’s Phase 2a clinical trial is a 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, the most common form of liver cancer. Enrollment of 31 patients in Italy, Greece, and Israel was completed on November 30, 2018.

The IDMC evaluated data from 28 out of the 31 patients who were evaluable. As of April 16, 2019, a total of 10 out of 27 patients have completed the study per protocol (6 cycles, 6 months). Four patients are still under treatment, while 3 are in cycle 6 and 1 is in cycle 5. Eight out of the 10 patients who completed treatment initially expressed interest to continue with treatment. Seven of these 8 patients were approved to continue with treatment under compassionate use by their respective Ethical Committees. Three of the patients under compassionate use have completed 9, 13, and 16 months of treatment with milciclib. The other 4 patients are continuing with treatment.

So far, no drug-related deaths have been recorded. Overall, the treatment with milciclib is well-tolerated with manageable drug-related toxicities. These safety and clinical activity are consistent with the earlier reported long-term safety and clinical activity of milciclib in thymic carcinoma, thymoma¹ and other solid cancers².

“Demonstration of safety and clinical activity is important milestone to move forward with strategic options for further clinical development of milciclib either as a single agent or in combination with one of the FDA approved drugs for treatment of HCC patients,” said Kunwar Shailubhai, CEO & CSO of Tiziana Life Sciences. We previously reported data from preclinical studies demonstrating that milciclib produced pronounced synergistic anti-HCC activity in combination with any one of the FDA approved drugs such as sorafenib (Nexavar®), regorafenib (Stivarga®), and lenvatinib (Lenvima®)³.”

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

For further enquiries:

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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 milciclib (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.
3. Jindal, A., Palejwala, V. and Shailubhai, K. (2018). Oral treatment with milciclib either alone or in combination with sorafenib inhibited tumor growth in an orthotopic model of hepatocellular carcinoma. Hepatology 68 Number 1 (Suppl): 879A (Abstract 1543)

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 (EMA) and U.S. Food and Drug Administration (FDA) 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, 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.
