Tiziana Life Sciences Provides Corporate Update

Tiziana Life Sciences plc is a publicly-listed (NASDAQ: TLSA; AIM: TILS) biotechnology company focused on the discovery and clinical development of innovative therapeutics for cancers, autoimmune and inflammatory diseases.

Major accomplishments in 2018 include the following:

- **On April 16, 2018, we entered into an exclusive license agreement with The Brigham and Women's Hospital, Inc. relating to a novel formulation of Foralumab dosed in a medical device for nasal administration. An investigational new drug application (IND) for the first-in-human evaluation of the nasal administration of Foralumab in healthy volunteers was filed in June 2018 and dosing for a Phase 1 trial to evaluate biomarkers of immunomodulation of clinical responses in healthy volunteers was initiated in November 2018. The study is expected to be completed by May 2019 and top line results are anticipated in 3Q 2019.**

- **An enteric-coated capsule formulation using a proprietary and novel technology has been developed for oral administration of foralumab. cGMP manufacturing of clinical trial materials for a Phase 1 study, in healthy volunteers, has been completed. The IND is expected to be submitted in 1Q, 2019. The clinical trial is expected to start dosing in 2Q 2019.**

- **We initiated a Phase 2a trial (CDKO-125a-010) of Milciclib safety and tolerability as a single therapy in sorafenib-resistant patients with HCC in July 2017. In May 2018, the Independent Data Monitor committee (IDMC) completed an interim analysis of tolerability data from the first eleven treated patients and recommended expansion of the initial cohort to an additional 20 patients to fulfil the trial enrolment, which was completed in December 2018. Top-line data is expected in 2Q 2019. Three patients have continued milciclib treatment on compassionate use, well past the average expected overall survival for HCC patients. One patient completed 9 months, and another completed 13 months of treatment with no apparent signs of toxicity. The third patient continued to receive the treatment and recently reached 16 months of treatment.**

- **Preclinical data on milciclib was recently presented at the AASLD meeting in November 2018. Significant tumour reduction in an orthotopic mouse model of HCC was demonstrated following five weeks of treatment with milciclib (-20% reduction, 30mg/kg/day)), sorafenib (-20% reduction, 20 mg/kg/day) and the combination of milciclib and sorafenib (-38% reduction) relative to vehicle control.**

- **Based on the synergistic effect of milciclib and sorafenib, we expect to initiate a Phase 2b trial (TZLS (201)-125a-011) dosing Milciclib in combination with sorafenib (the standard of care) in patients with HCC in 2019.**

The senior management team has more than 25 years of experience at leading biopharmaceutical and biotechnology companies with proven expertise in drug discovery, development and commercialisation. Our technical team comprises of leading medical scientists with deep knowledge and novel insights into disease mechanisms, along with a highly experienced clinical development team. Since its inception in 2013, Tiziana Life Sciences has expanded its pipeline to include clinical stage development therapeutic candidates. Milciclib's multifaceted mechanism of action inhibits multiple cyclin dependant kinases (CDKs) and tyrosine kinases (c-src and wee 1 & 2). It is currently being evaluated in a Phase 2a clinical study in sorafenib-resistant hepatocellular carcinoma (HCC) patients. Foralumab, a fully human anti-CD3 monoclonal antibody (mAb), is currently being developed via nasal administration for treatment of neurodegenerative diseases such as progressive multiple sclerosis (pro-MS) and amyotrophic lateral sclerosis (ALS). Additionally, Foralumab is being developed in an oral formulation for treatment of non-alcoholic steatohepatitis (NASH) and Crohn's disease.

Clinical Programs

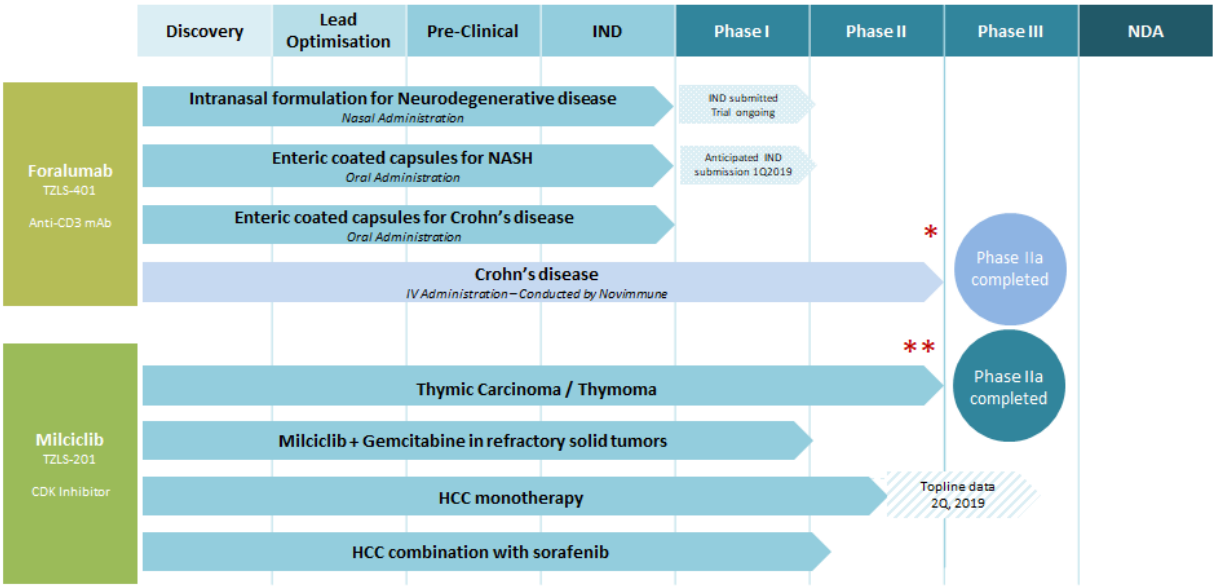
Tiziana is focused on targeting large markets with a high unmet medical need. Driven by an obesity and diabetes epidemic, non-alcoholic fatty liver disease (NAFLD) has become the most common liver disease, affecting one-third of the Western world. Between 3 and 5% of NAFLD patients progress to a more severe form of inflammatory

disease, known as NASH (non-alcoholic steatohepatitis), a progressive disease associated with chronic inflammation, fibrosis and cirrhosis in the liver. Based on data from US adult Liver Transplant (LT) databases, since 2004 the number of adults with NASH awaiting LTs has almost tripled. In 2013, NASH became the second-leading disease among liver transplant waiting list registrants, after the Hepatitis C virus. It is predicted that NASH may become the leading cause of liver transplantation in the United States by 2020.

The market for NASH therapies is estimated to reach £16.2 billion by 2025 (10.7% CAGR from 2015 to 2025). This anticipated growth has resulted in several high-profile M&A transactions, including four announced deals in 2016 totalling more than £2.3 billion in value. Around 20% of NASH patients progress further to cirrhosis of the liver, which may ultimately develop into fatal HCC, the primary cause of obesity-related cancer death in middle-aged men in the U.S. Liver transplants are the only effective option for end-stage patients, including HCC patients. More effective therapeutic agents to treat HCC are needed. Currently approved therapeutic agents are marginally effective and have significant safety issues.

Tiziana Life Sciences is focused on developing novel drugs for treatment of liver diseases with a pipeline of two clinical-stage drug candidates, Foralumab and Milciclib:

CLINICAL DEVELOPMENT PIPELINE



* The trial in Crohn's Disease (IV administration) conducted by Novimmune produced encouraging clinical response. TILS strategy is to pursue oral administration with foralumab in NASH and CD.

** We will seek guidance from regulatory authorities for next steps

Foralumab (TZLS-401 / NI-0401)

Foralumab is a fully human engineered anti-CD3 monoclonal antibody (mAB). It was in-licensed in December 2014 from Novimmune. In January 2016, Tiziana outlined its clinical development plan for Foralumab with initial plans to evaluate the drug in two clinical indications: non-alcoholic steatohepatitis (NASH) and inflammatory bowel disease (IBD).

As the only fully human engineered human anti-CD3 mAB in clinical development, Foralumab has significant potential advantages such as a shorter treatment duration and reduced immunogenicity. With completion of the intravenous dosing for our Phase 2a trial in Crohn's Disease, Foralumab's ability to modulate T-cell response enables potential extension into a wide range of other autoimmune and inflammatory diseases, such as GvHD, ulcerative colitis, multiple sclerosis, type-1 diabetes (T1D), inflammatory bowel disease (IBD), psoriasis and rheumatoid arthritis.

Foralumab is being developed as both an immunosuppressive and immunomodulatory agent, with therapeutic benefits of rendering T-cells unable to orchestrate an immune response and induction of immune tolerance via

maintenance of regulatory T-cells. There is further potential for Foralumab to be combined with the Company's TZLS-501, a fully human anti-IL-6R mAB in development to target autoimmune and inflammatory diseases.

In November 2016, Tiziana announced new data for oral efficacy in humanized mouse models with Foralumab, a major milestone and a potential breakthrough for the treatment of NASH and autoimmune disease. This unique oral technology stimulates the natural gut immune system and potentially provides a therapeutic effect in inflammatory and autoimmune diseases with greatly reduced toxicity. Positive therapeutic effects with Foralumab were consistently demonstrated in animal studies conducted by Prof. Kevan Herold (Yale University) and Prof. Howard Weiner (Harvard University).

On April 16, 2018, we entered into an exclusive license agreement with The Brigham and Women's Hospital, Inc. relating to a novel formulation of Foralumab dosed in a medical device for nasal administration. An investigational new drug application (IND) for the first-in-human evaluation of the nasal administration of Foralumab in healthy volunteers was filed in Q2 2018, and a Phase 1 trial to evaluate biomarkers of immunomodulation of clinical responses was initiated in November 2018. The study is expected to be completed by May 2019.

An enteric-coated capsule formulation using a proprietary and novel technology has been developed for oral administration of foralumab. cGMP manufacturing of clinical trial materials for a Phase 1 study has been completed and an IND is expected to be submitted in 1Q, 2019.

Milciclib (TZLS-201)

Milciclib, Tiziana's lead small molecule drug, was exclusively licenced in January 2015 from Nerviano Medical Sciences. Milciclib is an orally bioavailable, broad spectrum inhibitor of Cyclin Dependent Kinases (CDKs): 1, 2, 4, 5 and 7 and Src family kinases. Cyclin dependent kinases are a family of highly conserved enzymes that are involved in regulating the cell cycle. Src family kinases regulate cell growth and potential transformation of normal cells to cancer cells. A unique feature of Milciclib is its ability to reduce microRNAs, miR- 221 and miR-222, which silence gene expression. miR-221 and miR-222 promote the formation of blood vessels (angiogenesis) that are important for the spread of cancer cells (metastasis). Levels of these microRNAs are consistently increased in HCC patients and may contribute towards resistance to treatment with sorafenib. As a result, we are investigating Milciclib both as a monotherapy and as a combination treatment with sorafenib.

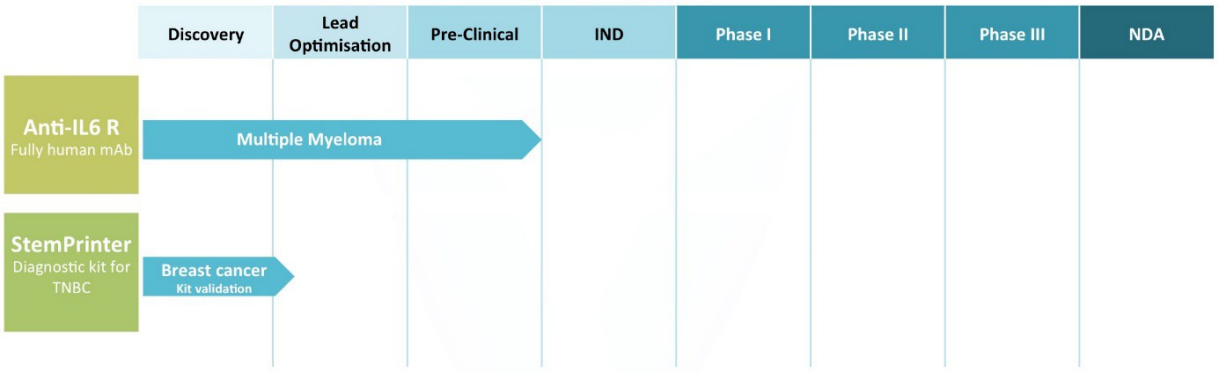
To date, Milciclib has been studied in a total of eight completed and ongoing Phase 1 and 2 clinical trials in 316 patients. In these trials, Milciclib was observed to be well-tolerated and showed initial signals of anti-tumour action. Prior to in-licensing, Milciclib was granted orphan designation by the European Commission and by the U.S. Food and Drug Administration ("FDA") for the treatment of malignant thymoma and an aggressive form of thymic carcinoma in patients previously treated with chemotherapy. In two Phase 2a trials, CDKO-125a-006 and CDKO125a-007, Milciclib showed signs of slowing disease progression and acceptable safety.

We initiated a Phase 2a trial (CDKO-125a-010) of Milciclib safety and tolerability as a single therapy in sorafenib-resistant patients with HCC in the first half of 2017. In May 2018, the Independent Data Monitor committee (IDMC) completed an interim analysis of tolerability data from the first eleven treated patients and recommended expansion of the initial cohort to an additional 20 patients to complete the trial enrolment, which was completed in December 2018. Top-line data is expected in Q2 2019. This trial is conducted in sorafenib-resistant HCC patients. Typically, this population of patients have an advanced form of the disease with poor prognosis and an average overall survival expectancy of 3-5 months. It is important to emphasize that 4 out of the 11 patients on treatment, completed 6 months in the trial and then requested continued treatment on a compassionate use basis. Subsequently, 3 patients were approved under the compassionate use program by the respective ethical committees. Among these three patients, one patient completed 9 months, and another completed 13 months of treatment with no apparent signs of toxicity. The third patient continued to receive the treatment and recently reached 16 months of treatment.

Preclinical data presented at the AASLD meeting in November 2018, demonstrated significant tumour reduction in an orthotopic mouse model of HCC following five weeks of treatment with milciclib (-20% reduction, 30mg/kg/day)), sorafenib (-20% reduction, 20 mg/kg/day) and the combination of milciclib and sorafenib (-38% reduction) relative to vehicle control.

Based on the expected synergistic anti-tumour effect of milciclib and sorafenib, we expect to initiate a Phase 2b trial (TZLS (201)-125a-011) dosing Milciclib in combination with sorafenib (the standard of care) in patients with HCC in 2019.

Pre-clinical Programs



In pre-clinical development, the Group has two programmes:

Anti-IL6R (TZLS-501)

TZLS-501 is a fully human engineered mAb targeting the interleukin-6 receptor (IL-6R). Tiziana Life Sciences licensed the intellectual property from Novimmune in January 2017. This fully human mAb has a unique mechanism of action that binds to both the membrane-bound and soluble forms of the IL-6R resulting in lowering of circulating levels of IL-6 in the blood. Excessive production of IL-6 is regarded as a key driver of chronic inflammation, associated with autoimmune diseases such as multiple myeloma, oncology indications and rheumatoid arthritis, and we believe that TZLS-501 may have potential therapeutic value for these indications.

In preclinical studies, TZLS-501 demonstrated the potential to overcome limitations of other IL-6 blocking pathway drugs. Compared to tocilizumab and sarilumab, while binding to the membrane-bound IL-6R complex TZLS-501 has shown a higher affinity for the soluble IL-6 receptor as seen from the antibody binding studies conducted in cell culture. TZLS-501 also demonstrated the potential to block or reduce IL-6 signalling in mouse models of inflammation. The soluble form of IL-6 has been implicated to have a larger role in disease progression compared to the membrane-bound form.[1]

StemPrinter

StemPrintER is a multi-gene signature assay intended for use in patients diagnosed with oestrogen-receptor positive ER+/HER2 negative breast cancers. We believe this in-vitro prognostic test will be used in conjunction with clinical evaluation to identify those patients at increased risk for early and/or late metastasis. StemPrintER is designed to help physicians distinguish ER+/HER2 negative patients:

- with an elevated risk of early recurrence (<5 years) who could benefit from chemotherapy in addition to hormonal therapy
- with a high risk of late recurrence who could benefit from prolonged endocrine treatment up to 10 years
- with a low risk of early recurrence who might be spared chemotherapy or be eligible for less aggressive treatments

Our diagnostic has a unique biological foundation based on the detection of cancer stem cell markers, uses a reliable platform (qRT- PCR, FFPE), and has been evaluated in an initial retrospective validation study using a consecutive cohort of approximately 2,400 patients with breast cancer. The development team is preparing for a retrospective validation study using an independent cohort and has conducted a pre- submission meeting with

[1] (Kallen, K.J. (2002). The role of trans signalling via the agonistic soluble IL-6 receptor in human diseases". Biochimica et Biophysica Acta. 1592 (3): 323–343.).

the FDA.

Financial

In November 2018, The Company announced pricing of its initial public offering of American Depositary Shares ("ADSs") representing ordinary shares of nominal value £0.03 each on the Nasdaq Global Market. The United States Securities and Exchange Commission declared it effective with a registration statement relating to such securities on 19 November 2018 and the ADSs were listed for trading on such market under the symbol "TLSA" on 20 November 2018. The Company raised gross proceeds of $ 4.4 million by offering 442,910 ADS's at $9.90. In addition to the $4.4 million raised in the US IPO, the Company also raised $1.5 million in an equity offering in late October and $1.4 million by issuing shares in relation to exercised warrants and issued new shares to extinguish $1.8 million in debt. The Company raised in total gross proceeds of $7.3 million.

Outlook

We have continued to progress our pipeline of drugs to treat rare cancers and difficult to treat autoimmune and inflammatory diseases.

We have outlined our clinical development plan for Foralumab with initial plans to evaluate orally-dosed Foralumab in two clinical indications: NASH and Crohn's disease. The IND for nasal administration for neurodegenerative diseases was submitted in November 2018 and the trial in ongoing smoothly. The IND for oral administration is anticipated to be submitted by March 15, 2019.

For Milciclib, two Phase 2 clinical trials for thymic carcinoma (thymoma) in patients previously treated with chemotherapy were completed. A Phase 2 monotherapy trial using milciclib to treat patients with hepatocellular carcinoma (HCC) is ongoing and the topline data from this trial is anticipated to be available by July 2019. We expect to commence a Phase 2b combination therapy trial dosing HCC patients with milciclib and the standard of care, sorafenib, in the 2H, 2019.

Looking ahead, we are confident that Tiziana is well positioned to advance these programs to their next respective value inflection points.