TIZIANA LIFE SCIENCES PLC (NASDAQ:TLSA)

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proactive research

Healthcare

52-WEEK HIGH	**$3.29**
52-WEEK LOW	**$0.53**
PRICE	**$1.19**
MARKET CAP MLN	$121.17

Share Price

Major Shareholders

Shares in issue	194,612,289
Avg Three-month trading volume	316,663
Primary Index	NASDAQ

Company Information

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Kunwar Shailubhai, chief executive/chief scientific officer (CSO). He was also a co-founder, executive vice-president and CSO of Synergy Pharmaceuticals, the inventor of TRULANCE. He is a pioneer of GC-C agonist technology. Other former roles include vice president of Callisto Pharmaceuticals and Group Leader at Monsanto Co.

Gabriele Cerrone, executive chair. He has a track record of corporate financing having listed nine companies, seven on NASDAQ and two in London. He is the former chair of Trovagene, Gensignia, Rasna, Contravir and Okyo. He is also the co-founder and director of two NASDAQ-listed companies that brought drugs from the discovery through to US Food

Second SPMS patient shows response, trial expands

Tiziana continues to see promising results in SPMS

Tiziana Life Sciences has reported that positive imaging and functional results have been seen in the second patient with secondary progressive multiple sclerosis (SPMS) enrolled in its expanded access study of intra-nasally delivered foralumab. The data points were measured after three months of treatment and are consistent with the results seen in the first patient. Furthermore, as a result of this and the favourable safety profile, the US Food & Drug Administration (FDA) has allowed the study to be expanded to treat up to eight patients and potentially test a higher dose of 100mcg (versus 50mcg) if patients appear to benefit.

The study is being conducted at Boston's Brigham and Women's Hospital, one of the leading teaching hospitals in the US. It enrols patients with SPMS, a type of disease occurring typically at a later stage where the disability is already significant and gets progressively worse despite disease-modifying therapies.

The second patient is a male in his 40s who was diagnosed with SPMS in 2014. After three months of treatment with foralumab (50mcg; three times a week for two weeks, followed by one week off), the patient showed improvements, as measured by PET imaging (to assess inhibition of microglial activation) and by neurologic examination. A ~10-30% reduction in PET signal was seen across brain regions (including cortex, thalamus, white matter, and cerebellum) in the patient, which is comparable to the PET changes seen in the first patient at three months. The patient also recorded improvements in the Timed 25-Foot Walk test (T25FW, time to walk ~7.2m), a functional endpoint.

The results are consistent with the previously reported data from the first SPMS patient and both patients are now continuing on the drug and are in their 13th and 4th months of treatment, respectively. Tiziana and the investigators at Brigham and Women's recently presented a poster on the first patient at an MS scientific conference (this has the data released in March). This confirms that the patient, a 61-year-old male with SPMS for over 20 years, had previously seen his condition progressively worsen despite more than three years of treatment with ocrelizumab (Ocrevus, Roche), which is considered the most effective drug available for SMPS. The patient showed an improvement in his T25FW from ~40s to ~20-30s over three months on foralumab (this also gives an indication of the extent of the accumulated disability in SMPS).

Conclusion

The latest data are still effectively a clinical anecdote but are consistent with the first patient and are suggestive of efficacy in patients who have exhausted all other therapeutic options. Further results may come next year and the next stage, perhaps in 2023, could be an open-label Phase 2 study in 10-20 patients. This data may allow Tiziana to partner the drug, which would be required to conduct the large (and very expensive) randomised controlled studies needed to support approval.

& Drug Administration approval: Synergy Pharmaceuticals and Siga Technologies.

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