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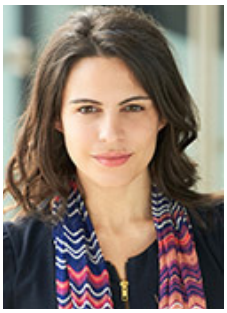
Stalicla's series B adds $17.4M for trials in substance abuse disorders, ASD

By Nuala Moran, Staff Writer

Stalicla SA announced the first close of a series B round at $17.4 million, which provides the means to complete preparations for both a phase III trial of the lead program, STP-7, in the treatment of cocaine misuse disorder, and of a phase II trial of STP-1 in autism spectrum disorder (ASD).

The phase III study of STP-7 – aka mavoglurant, an mGluR5 negative allosteric modulator – will be funded by the U.S. National Institute on Drug Abuse (NIDA). But before the study can get underway in 2025, Stalicla needs to complete CMC quality work on the drug.

In the case of STP-1, the series B money enables Geneva-based Stalicla to apply its precision medicine technique for endophenotyping patients with neurodevelopmental disorders (NDDs), to identify a subgroup of ASD patients with similar molecular signatures. It is expected that more than 1,000 patients will be screened to identify likely responders for inclusion in the phase II trial.



Lynn Durham, founder and CEO, Stalicla

Endophenotyping goes beyond diagnosing NDDs on the basis of behavioral symptoms, using metabolomics, and whole genome and RNA sequencing, to decode the underlying mechanisms and causal factors and stratify patient populations.

That also forms the basis for looking for approved drugs that can be repurposed, or for drugs that have shown some effect in NDD clinical trials but failed to reach statistical significance.

Stalicla's original intention when it in-licensed mavoglurant from Novartis AG a year ago, was to focus on taking it forward in the treatment of NDDs.

While the drug had failed in two trials in fragile X, the most common inherited form of intellectual disability and a leading cause of autism, there was a lot of positive feedback from clinicians, families and carers, who reported improvements in symptoms. Stalicla reasoned its precision medicine approach could help identify patients who would respond.

However, mavoglurant had turned in positive results in a 68-participant trial in cocaine use disorder, in which those who took the active drug reported using cocaine less frequently than participants in the placebo arm.

"Originally, we believed in its potential in neurodevelopmental disorders, which is the core of what we do," said Lynn Durham, founder and CEO of Stalicla. Subsequent investigations pointed to the potential of developing mavoglurant as a treatment not only for cocaine addiction, but for multiple substance use disorders.

"The mechanism of action of mavoglurant is to engage the mGluR5 receptor, which is highly abundant in the reward system in the brain," Durham said. So the mechanism is not specific to a specific substance of abuse, but rather to a mechanism that generates an abuse disorder," she told *BioWorld*.

The company is in discussions with government agencies about investigating the use of mavoglurant in alcohol use disorder. Another potential application is in treating fentanyl addiction.

"It's absolutely critical that mavoglurant comes to serve all the patients that would need it, regardless of the substance of abuse. And that is the plan of the U.S. government agencies, and we are in discussions with them," said Durham.

Mavoglurant already has a hefty safety file, having been tested in more than 1,800 clinical trial participants. But before the phase III cocaine trial can go ahead, NIDA is conducting a drug-drug interaction study, and Stalicla needs to do CMC and manufacture supplies of the drug, because all the previous batches have expired.

This is being used as an opportunity to build in new intellectual property. Durham did not want to give any details of how that will be achieved, but said, "Part of the strategy is to optimize things so we have commercial protection for as long as possible."

In addition, some of the series B money will be invested in positioning mavoglurant as a technology platform that can be applied across neurological indications.

To take these other indications forward, Stalicla will need to raise more money, and Durham said leading VCs already

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Continued from previous page

have expressed an interest. "They now see the potential [of mavoglurant] on the substance abuse side – which was disregarded in the past," she said.

The first close of the series B was led by SPRIM Global Investments Pte Ltd., with participation from other investors. The funding includes a $3.8 million credit facility.

Funneling trials

While preparations for the phase III cocaine use trial proceed, the majority of the $17.4 million round will go to progressing the STP-1 ASD phase II study.

After identifying ASD patients with similar disease signatures, these subgroups are matched to an NDD-targeted drug, or drug combination. Stalicla has not disclosed what drug is being tested in the STP-1 program, but it has validated it in a small trial.

"The sample size was small, but the results were very encouraging because we had a very strong target engagement," said Durham. That positions STP-1 for a larger phase II.

"We're operating under a precision medicine model, and that means we have to run biosampling observation trials that allow us to pre-recruit patients, to then dose them in clinical trials. That's the main purpose of this capital raise," said Durham.

The scale of this undertaking is significant: It is estimated that it will be necessary to screen 40 patients to identify one patient who would be eligible for the phase II, she said.