

Tioga Formed To Develop Merck KGaA's Asimadoline

By Jennifer Boggs, Staff Writer

A Phase II compound for gastrointestinal diseases that was shelved by Merck KGaA has gained new life with Tioga Pharmaceuticals Inc., a Merck spinout founded by investment firm Forward Ventures.

Since it began narrowing its pipeline to focus on cardiovascular and oncology products, Darmstadt, Germany-based Merck has been divesting assets. That includes asimadoline, a kappa-opioid agonist that has shown promising results in preclinical and early clinical studies as a treatment for irritable bowel syndrome.

Forward Ventures, which previously had worked with Merck to form the vascular biology company, TargeGen Inc., convinced the German company that asimadoline would stand a greater chance of success if it were developed by a new company that could focus solely on its progress, "rather than it being one of 100 clinical projects inside big pharma," said David Urso, principal at Forward Ventures and acting chief business officer of Tioga.

"I think [Merck] was persuaded by that argument," he added. "We negotiated terms for acquiring asimadoline and then set up Tioga."

San Diego-based Forward Ventures completed an undisclosed Series A financing for Tioga in mid-June. Merck holds an equity interest in the new company and will be entitled to receive royalties on product sales.

Urso said the attraction of asimadoline, believed to be efficacious in treating abdominal pain associated with irritable bowel syndrome (IBS), is due to Merck's reputation in drug development, as well as promising study data.

Having already been tested in more than 500 subjects, asimadoline has generated substantial safety data, Urso told *BioWorld Today*, adding that results from a Phase IIa trial in 20 IBS patients, as measured by a barostat, showed a significant reduction in pain.

"We're really excited about this," he said. "It's rare to get a hold of a quality asset like this."

Tioga will begin by initiating Phase II trials in IBS, though the drug could be investigated later as a treatment for other indications, such as post-operative ileus.

"Right now, we're trying not to get too distracted with other indications, or trying to look for other drugs to license in," Urso said. "That might be something we explore in the future."

In addition to Urso, Tioga's executive staff comprises acting CEO Stuart Collinson, a partner at Forward Ventures, and Chief Medical Officer Allen Mangel, who previously headed gastroenterology product development at London-based GlaxoSmithKline plc. Urso, Collinson and Merck's Arno Hartmann make up the board, and the company is looking to put together a clinical advisory board before finalizing the Phase II trials plans.

Tioga also will start to bring on employees, though Urso said the goal is to keep operations "substantially virtual" to avoid creating a large infrastructure that relies on a heavy burn rate.

"I think there's a lot of pressure just to keep the amount of money that's going into private companies down," he said, referring to the low valuations of recent initial public offerings, and the difficulty in raising funds in the existing market.

Tioga's next step will involve putting together a syndicate and raising additional funds to begin the Phase IIb trial.

"We're just beginning to introduce the deal to other venture groups," Urso said.

He estimated having data from the Phase IIb trial in hand as early as 18 months after closing the next financing round. Those results likely will determine the company's direction.

"I think our options would be to partner the product and maybe look to establish a franchise in gastroenterology," he said, "or possibly sell the company. We'll have to see how good the data is, what kind of demand there is for the product and what the market conditions are at the time, and then decide where we go from there." ■