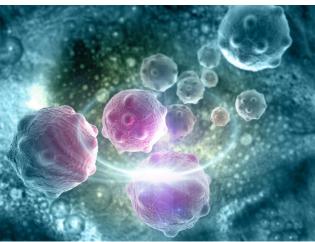
## Onconano Medicine lands \$50M in series B to spur nanosensor that 'lights up' cancer



June 22, 2021 By Ana Mulero

Onconano Medicine Inc. raised around \$50 million in series B financing to accelerate the momentum of its technology designed to diagnose and treat cancer with high specificity. The biotech company's nanosensor works by reacting to low pH and illuminates cancer like a lightbulb, distinguishing cancerous tissue from healthy tissue. This is intended to make it easier for surgeons to remove cancer cells while leaving healthy, functional tissue intact.

The company's product candidates exploit pH as a biomarker to help patients across the continuum of cancer care, from diagnosis to treatment, and have been gaining momentum in recent years. They include solid tumor therapeutics, agents for real-time image-guided surgery, as well as a platform of product candidates that activate and guide the immune system to target cancer.

The financing was led by the health care investment team at Advantech Capital, a China-based institutional investment fund. Proceeds will be used to support the phase III trials in the U.S. and Europe for the real-time imaging agent, called pegsitacianine, for use in intraoperative surgical resection, or cutting out, of solid tumors. The company also intends to use the proceeds of the new financing to speed up the advancement of its first therapeutic development program, ONM-501, a novel immune-therapeutic that was formulated using the company's core delivery technology.

"We are impressed with the potential for Onconano's innovative core technology," said Benjamin Qiu, a partner at Advantech Capital. Advantech Capital sees "great promise in Onconano" and is "excited to support the company through its further advancement of pegsitacianine into a pivotal clinical development program." It is also excited to support advancing its dual-activation STING (STimulator of INterferon Genes) agonist towards a first-in-human study "to help address the persistent and challenging unmet needs in cancer surgery and treatment." This is slated for the second half of 2022.

Previous investors include Salem Partners LLC, a Los Angeles-based investment bank and wealth management firm, which arranged the series A financing where Onconano raised an additional \$23.7 million that brought the total to \$35.4 million in 2019, and whose founder sits on Onconano's board of directors, along with executives at biotech companies Renibus Therapeutics Inc. and Illumina Inc.

Onconano also received a \$15.4 million grant from the Cancer Prevention and Research Institute of Texas in 2019. The series A round and the series B round bring the company's total capital raised thus far at around \$85 million. The company is the recipient of \$31.4 million in grant awards from the Cancer Prevention & Research Institute of Texas (CPRIT), nearly \$24 million of which is still to be drawn down.

"We are thrilled to welcome Advantech as an investor in Onconano and look forward to continuing the momentum we've built with our lead development programs that utilize our proprietary pH-activated micelle platform," said Onconano CEO Martin Driscoll, CEO. The plan is to initiate the pegsitacianine pivotal trial program in the U.S. and Europe and submit an investigational new drug application (IND) for the first therapeutic development program in 2022.

The funds from the new financing coupled with the support of the CPRIT provide the resources for the company to stay in business for several years, further advance its pegsitacianine towards commercialization, and progress the immuno-oncology compound ONM-501 through the company's phase Ia/Ib program. "With the inclusion of the new capital, we now have the capability to accelerate our development programs and work to achieve our goal of bringing novel interventions and treatments to cancer patients," said Driscoll.

## Lighting up cancer

Surgical resection remains a cornerstone treatment strategy for solid tumors and incomplete tumor removal can be predictive of cancer recurrence and metastasis. Despite imaging advances, there are currently no approved imaging options to provide real-time feedback to surgeons that specifically target tumor masses but are agnostic to cancer type. Onconano aims to change this in the near future.

The company was formed in 2014 as a spinout of the University of Texas Southwestern. It is now financed to advance its programs for more than three years, Driscoll told *BioWorld*.

The company will expand the number of tumor types studied in its clinical development program for pegsitacianine, including lung and breast cancer. It will now also advance

its second oncology therapeutic program. "We will disclose the identity of this second therapeutic development program later this year as we generate additional nonclinical proof of concept data," he said.

Pegsitacianine, is a fluorescent nanoprobe and it is currently under study in phase II trials as a real-time surgical imaging agent for use in multiple cancer surgeries.

A surgeon and a professor at the UT Southwestern Medical Center – which licensed the technology to Onconano and has a financial interest in the research – previously collaborated to develop the nanoprobe sensor and integrated it with a clinical camera that allows the surgeon to see the fluorescent areas in the body during a surgical procedure. The nanosensor not only lights up cancer but also suppresses the signal in normal tissue, helping the surgeon to clearly distinguish between cancer and healthy tissue. It is expected to be effective in all solid tumors.

"This new digital nanosensor-guided surgery has several advantages for patients, including more accurate removal of tumors and greater preservation of normal tissue," said co-developer Baran Sumer from the head and neck oncology team at UT Southwestern Medical Center's Simmons Cancer Center. "These advantages can limit the extent of surgery and improve quality of life and, potentially, patient survival."

Breast cancer patients at the University of Groningen in the Netherlands, which is collaborating in the trials, were first to be treated with the new technology. Patients were intravenously injected with the nanosensor medication about 12 hours before surgery and tumors were observed to light up and remain fluorescent for one to two days.

Phase I trial data were published in *Nature Communications* last June. Following tumor resection, the immuno-oncology compound detected residual tumor positive margins in all nine of nine patients in whom histology confirmed tumor positive margins. It also detected occult lesions in an additional five patients whose tumors were undetected by standard of care, the results show.

Onconano plans to generate data from its phase II study of pegsitacianine in head and neck squamous cell carcinoma later this year and expects to "reach important milestones in 2022," Driscoll said. These milestones include generating data from phase II studies for pegsitacianine in peritoneal metastases and lung cancer, initiating a phase III program for pesitacianine, launching the company's first trial in Europe, and submitting the IND for ONM-501.

The company is currently involved in two research agreements with two major pharmaceutical firms that involve the formulation of their oncology therapeutics with its polymeric micelles, according to Driscoll. "This core technology at Onconano seeks to deliver an anti-cancer payload to a solid tumor and exploit the pH environment of the tumor microenvironment," Driscoll added. "Data from these research collaborations could be available by early next year."