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EMERGING COMPANY PROFILE

Vineti: Keeping cell therapies on track

BY MARK ZIPKIN, STAFF WRITER

Drawing on its experience with CAR T cell therapies, Vineti has developed a cloud-based software platform that standardizes processes and drives down costs in the supply chain for personalized medicines.

According to Vineti Inc. CEO Amy DuRoss, the company was incubated at GE Ventures after an undisclosed company approached the investor in 2014 about a CAR T cell therapy then in clinical trials.

"They realized it really presented them with the most complex supply chain of logistics workflow requirements in the history of biologics -- really, in the history of medicine," said DuRoss, who co-founded the start-up when she was at GE Ventures.

This was the first time single-batch GMP processes had to occur at the point of care for trials and marketed personalized medicines, and that created a need for GMP-level oversight of cell handling and the orchestration of material handoffs between multiple stakeholders, she said.

Autologous CAR T cell therapies such as Novartis AG's Kymriah tisagenlecleucel and Gilead Sciences Inc.'s Yescarta axicabtagene also involve challenges with collection, manufacturing and logistics not typical for traditional drug therapies, and the processes can become unwieldy for sponsors to manage manually.

Manual processes lack the real-time transparency and control that cloud-based automation offers, and their inefficiencies have contributed to the high cost of personalized cell and gene therapies, DuRoss said. "Pharma has been such a lagging adopter of cloud-based technology" and as a result, the internal systems created so far have been "clunky."

DuRoss said the challenges around autologous cell therapies, and the need to control costs through standardization, led to the formation of Vineti, which developed cloud-based software for verifying chain of custody and identity documentation to meet GMP protocols. Vineti's platform is built on configurable modules that can adapt to the complexities required of cell therapy supply chains, such as validating cell identities at clinical sites that typically aren't GMP-compliant.

VINETI INC.
San Francisco, Calif.

Technology: Cloud-based software platform organizing workflows, data collection and management, supply chain logistics and production of cell-based and other personalized therapies

Disease focus: NA

Clinical status: NA

Founded: 2016 Amy DuRoss, Razmik Abnous, Rowan Chapman, Malek Faham, Heidi Hagen, Barmak Modrek and Stephen Ting

University collaborators: NA

Corporate partners: GE Ventures, Mayo Clinic

Number of employees: 85

Funds raised: $47.3 million

Investors: Canaan, DFJ Ventures, GE Ventures, Section 32, Casdin Capital, LifeForce Capital, other undisclosed investors

CEO: Amy DuRoss

Patents: None issued

Real-time monitoring at multiple sites is beneficial for timing a patient's pretreatment conditioning and cell collection with the availability of manufacturing capacity.

"Each patient is a 'batch of one,'" said Heidi Hagen, co-founder and chief strategic officer of Vineti. "Once you are trying to manage more than 10 patients in a single trial, manual processes often become unsustainable."

Hagen said the platform is at least 20-30% less expensive than processes biopharmas might develop in-house.

Vineti's software can be deployed for allogeneic or autologous cell workflows because the software's modules can connect to the external systems of the company's clients and the clients' clinical, manufacturing and logistical partners. The platform meets draft FDA safety guidelines announced last year on establishing clinical trial infrastructure to allow for the rapid assessment of emerging

data in real time: Vineti's cloud-based software allows clinical sites, manufacturers and sponsors access to data and logistics information as it is collected.

At least one other company, TrakCel Ltd., offers cloud-based supply chain management platforms to biopharma clients. DuRoss said that compared with TrakCel's tech, Vineti's platform incorporates a greater degree of standardization and is more readily usable by multiple stakeholders.

Matthew Lakelin, TrakCel's VP of scientific affairs and business development, said while standardization has some advantages, companies in clinical development are often uncertain which steps will be most important to their processes, and so TrakCel customizes its software to suit each client's needs.

Vineti's is the only third-party workflow software whose use is publicly disclosed for a commercial CAR T cell therapy: Yescarta, which is marketed for refractory B cell and follicular lymphomas.

DuRoss said companies much larger than Vineti, such as drug distributors with footholds in drug supply chain management, may try to develop software that can handle the unique chain of identity demands of the cell therapy space. But she thinks Vineti remains well positioned because of its expertise in GMP manufacturing, enterprise technology, and CAR T supply chain and delivery.

While most of Vineti's clients are working in autologous therapies, there is growing interest in applying it to allogeneic therapies, neoantigens and other personalized therapies, DuRoss said. Vineti has three other disclosed biopharma clients: Autolus Therapeutics plc, Marker Therapeutics Inc. and Tessa Therapeutics Pte. Ltd.

Vineti raised a $33.5 million series B a year ago led by Canaan and DFJ Ventures. DuRoss did not disclose the company's runway, but said it will spend the next few years expanding the platform and deepening configurability to interface with new partners. bc

COMPANIES AND INSTITUTIONS MENTIONED

Autolus Therapeutics plc (NASDAQ:AUTL), London, U.K.
Gilead Sciences Inc. (NASDAQ:GILD), Foster City, Calif.
Marker Therapeutics Inc. (NASDAQ:MRKR), Jacksonville, Fla.
Novartis AG (NYSE:NVS; SIX:NOVN), Basel, Switzerland
Tessa Therapeutics Pte. Ltd., Singapore
TrakCel Ltd., Cardiff, U.K.
Vineti Inc., San Francisco, Calif.

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