

Emerging Company Profile**Quantum Immunologics: Going to school**

By Stephen Hansen
Staff Writer

Quantum Immunologics Inc. is developing an autologous dendritic cell therapy that it says applies lessons learned from **Dendreon Corp.**'s path through the clinic with Provenge sipuleucel-T.

Where Quantum says it is differentiated from other cancer immunotherapy companies is the antigen it uses to target the cancer cells, a cell surface receptor known as oncofetal antigen/immature laminin receptor protein (OFA/iLRP).

"If you look at historical data and references, over 85% of patients with stage IV metastatic breast cancer will express OFA," said Eric Olle, director of research. At least 44% of breast cancer patients in general express OFA, and he said so far all forms of cancer tested by the company have been found to express OFA to some degree. The company said these include more than 500 cancer types.

Olle said its therapy should have a good safety profile because "OFA is very rarely or not at all expressed in normal tissue."

Similar to Provenge, which last month submitted an amendment to its BLA for treatment of advanced prostate cancer, Quantum's immunotherapy is an autologous dendritic cell therapy in which the antigen is added *ex vivo*.

A blood sample is taken from the patient and processed at an external facility to isolate monocyte-derived dendritic cells. OFA/iLRP is added, and the DCs are then matured, harvested and re-injected into the patient. The re-injected DCs present the antigen to the immune system, which activates T lymphocytes to target the cancer cells expressing OFA/iLRP.

Quantum said it uses GM-CSF in the maturation process of the dendritic cells, but the immunostimulant is not used during therapy because the company does not believe it will be necessary.

Quantum in-licensed the therapy and accompanying IP from the **University of South Alabama**.

Quantum Immunologics Inc.

Tampa, Fla.

Technology: Autologous dendritic cell immunotherapy containing oncofetal antigen/immature laminin receptor protein (OFA/iLRP)

Disease focus: Cancer

Clinical status: Phase I/II

Founded: 2008 by Charles Broes

University collaborators: University of South Alabama

Corporate partners: None

Number of employees: 18

Funds raised: Undisclosed

Investors: Private individuals

CEO: Charles Broes

Patents: Two issued patents covering the use of OFA in immunotherapies for cancer

As it has moved into clinical development, the company has been mindful of the Dendreon experience, in which Provenge missed the primary endpoint of delay in time to disease progression in two Phase III trials before achieving the primary endpoint of overall survival earlier this year in the subsequent Phase III IMPACT trial (see *BioCentury*, April 20).

Quantum is conducting a Phase I/II trial of an unnamed immunotherapy in 27 stage IV metastatic breast cancer patients. The company expects to complete the study by year end or January 2010, with data expected soon after.

The primary endpoint is safety, but Chairman and CEO Charles Broes told *BioCentury* one thing Quantum learned from Dendreon's early failure and more recent success is that efficacy trials need to have a survival endpoint, rather than looking at endpoints with shorter time frames such as time to progression or response rates.

Thus the next trial, most likely a Phase IIb involving around 200 patients, would have overall survival as the primary endpoint. He said such a trial would likely take about two years.

Broes also said Quantum learned from Dendreon that treatment protocols need the flexibility to allow for additional doses of the immunotherapy should the patient need it. Quantum's IND included "a variable to the treatment protocol, so that if the independent investigator determines that a particular patient should have additional treatments, they are able to do so up to a maximum of three additional treatments," he said.

The treatment protocol for Quantum's Phase I/II trial involves three doses one month apart.

Chief Investment Officer Josh Coughlin said Quantum is open to the idea of taking the immunotherapy into Phase II or even Phase III trials. The company has been financed by private investors, but larger trials would require financing from VCs.

Coughlin expects to start the dialog with potential partners and VCs as the Phase I/II data begin to come in during the first quarter of next year.

The company also is working to develop blood-based tests for treatment monitoring and a screening test based on the OFA/iLRP target. Both are in early preclinical development.

Quantum said the monitoring test might be used to monitor the remission process of the cancer or at regular intervals to ensure the effectiveness of the immunotherapy. The company said that because the monitoring test is still in early preclinical development, it is unclear whether it will be incorporated into future clinical trials of the immunotherapy.

COMPANIES AND INSTITUTIONS MENTIONED

Dendreon Corp. (NASDAQ:DNDN), Seattle, Wash.

Quantum Immunologics Inc., Tampa, Fla.

University of South Alabama, Mobile, Ala.

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