Oncology Venture: Enrichment tool

By Georgina Sket
Staff Writer

Oncology Venture ApS has an exclusive license to a computational method to predict patient response to cancer therapies that could provide an efficient and cost-effective way to repurpose compounds that have failed in prior cancer trials and to find new cancer indications for marketed drugs.

The method comprises an undisclosed algorithm that inputs publicly available transcriptomics data from the NCI-60 panel of tumor cell lines and genomics data from about 3,000 patient biopsies. The output is a signature known as a drug response predictor (DRP).

The DRP is used to analyze samples from cancer patients and predict the likelihood patients will respond to a given therapeutic. The DRP also predicts which cancer indication will have the highest number of responders.

The company has DRPs for about 75 undisclosed compounds. Oncology Venture exclusively licensed the DRPs from the Medical Prognosis Institute A/S, which will produce other DRPs for the biotech’s programs in return for 10% of the company’s future profits.

Oncology Venture will use DRPs to develop compounds that were halted in clinical trials or to find additional indications for marketed oncology drugs, or other drugs that can kill cancer cells or inhibit their growth.

“Oncology Venture was created to make a fast evaluation of interesting compounds, and to screen hundreds of patients but only treat the high likelihood responding patients, expecting to increase response rates from lower than 10% to at least a 30% response,” said CEO Peter Jensen.

The ability to drive up trial response rates would mean fewer patients would have to be treated to demonstrate statistically significant efficacy.

Jensen said the company tested its DRPs by using them to predict the outcome of 24 published clinical cancer trials for which clinical and gene expression data were available. He said the DRPs predicted the primary endpoint with statistically significant accuracy in 20 of the trials.

Jensen, who was CEO of Topotarget A/S, cited belinostat as an example of how the technology could have made an impact, saying a DRP would have cut the time to develop the compound to five years instead of at least 11.

Belinostat is a small molecule histone deacetylase (HDAC) inhibitor for which Topotarget expects partner Spectrum Pharmaceuticals Inc. to submit an NDA to FDA this half.

More than 1,000 patients were enrolled in 22 Phase I and Phase II trials. The patients were selected based on the “best animal models available,” according to Jensen.

Using a DRP would have shown that peripheral T cell lymphoma (PTCL) patients had higher response odds and thus would have been enrolled earlier in clinical development, he said. Fewer patients overall would have been necessary to show statistical significance, and the trial
would have taken less time.

"It’s easy to be wise in hindsight, but it’s a sixfold reduction in cost, extension of patent protection, increased use of belinostat, and other indications for which we can screen for activity for off-label use," said Jensen.

In November, Oncology Venture acquired exclusive, worldwide rights to another Topotarget compound, APO010. It is a recombinant fusion protein consisting of three human Fas ligands (TNF superfamily, member 6; FASL).

In 2009, Topotarget completed a Swiss Phase Ia trial of APO010 in 25 patients with solid tumors. The compound was well tolerated at doses of up to 45 µg/m². However, Jansen said development was halted because of financial constraints.

Oncology Venture plans to start Phase I testing of APO010 next quarter to treat breast cancer and multiple myeloma (MM).

According to the company, a DRP is expected to increase the Phase III response rate to 57% from an estimated 25% by enrolling likely responders.

The estimated cost of conducting the trial with the DRP would be about $7 million, compared to $72 million without.

Oncology Venture will in-license rights to compounds. According to Jensen, the plan is to “develop five products in a three-year period, evaluate the products, and obtain partnerships on at least two.”

Jensen said the company plans to raise about €10 million ($13 million) in seed funding within the next two quarters.

The company is seeking a combined patent to the algorithms covering about 60 compounds.

COMPANIES AND INSTITUTIONS MENTIONED

Medical Prognosis Institute A/S, Horsholm, Denmark
Oncology Venture ApS, Copenhagen, Denmark
Topotarget A/S (CSE:TOPO), Copenhagen, Denmark
Spectrum Pharmaceuticals Inc. (NASDAQ: SPPI), Henderson, Nev.