InterVenn BioSciences Hits Commercial Phase, Launches Test for Immunotherapy Response in Melanoma
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NEW YORK – (GenomeWeb)

Backed by data from a 200-person clinical study, glycoproteomics firm InterVenn Biosciences has released its first commercial product, a mass spectrometry-based test for guiding immunotherapy in melanoma patients.

Called Dawn IO Melanoma, the test is intended to determine whether advanced melanoma patients are likely or unlikely to respond to treatment with immune checkpoint inhibitors, specifically either Merck's Keytruda (pembrolizumab) alone or Bristol-Myers Squibb's Yervoy (ipilimumab) in combination with BMS's Opdivo (nivolumab).

South San Francisco-based InterVenn launched the test this week as a laboratory-developed test, at the same time it is presenting a poster on its development and validation at the American Society of Clinical Oncology annual meeting in Chicago.

John Leite, the company's chief business officer, said it plans to market the test initially to integrated healthcare networks and capitated systems where it believes it can help more efficiently manage treatment costs by identifying patients unlikely to respond to immune checkpoint inhibitors, as well as to integrated systems and academic medical centers running clinical trials that might provide other treatment options for patients identified by the test as probable non-responders.

"We're expecting to really play up the health economics where we are playing two factors", he said. "There is the overall outcomes, and then, if you're not deriving benefit from [immunotherapies], what else is there? Many of these [integrated providers] are very sophisticated and are starting to make their systems available to clinical trials from pharma for next-generation checkpoint inhibitors or new combinations".

Leite said the company was currently developing its health economic model for the test, and added that InterVenn will target the broader healthcare market once it has lined up reimbursement for the test, noting that the company is currently in discussions with Medicare and private payors.

InterVenn was launched in March 2018 to commercialize glycoproteomic analysis methods developed by University of California, Davis professor Carlito Lebrilla and Stanford University professor Carolyn Bertozzi, both cofounders of the firm. Protein glycosylation, in which sugars modify various amino acids, is a common post-translational modification and an important phenomenon in the biology of various diseases, including many cancers. Given this, researchers have long considered glycoproteins to have high potential as biomarkers, and, in fact, more than half of the cancer protein markers currently approved by the US Food and Drug Administration are glycoproteins.

InterVenn developed Dawn IO Melanoma in collaboration with researchers at Massachusetts General Hospital. Using its mass spec platform, the company analyzed pre-treatment blood samples from a cohort of 205 advanced melanoma patients at MGH and measured 532 glycopeptides on 75

proteins. The researchers used 81 of the 205 patients as a training set to develop a glycoproteomic classifier for predicting response to immunotherapy and then validated the signature with the remaining 124 patients from the cohort.

In the validation set, the test identified 100 patients as likely to benefit, 14 as unlikely, and 10 whose results were indeterminate. Median progression-free survival in the likely-to-benefit group was 17.3 months, while median PFS in the unlikely to benefit group was 2.5 months, with a hazard ratio between the two groups of 4.9.

The company has also evaluated the test in a cohort of patients from an academic center in Australia and saw what Leite said were results comparable to the MGH validation work, though it has not released that data.

Tillman Pearce, InterVenn's chief medical officer, said the company thought the test could be particularly useful given that PD-L1 has not shown utility for assessing likelihood of patient response to immunotherapy in melanoma and, in fact, the National Comprehensive Cancer Network guidelines say doctors should not use that marker for clinical decision-making in melanoma.

Immunotherapies, or IO, "has really come on like a hurricane in melanoma in terms of how rapidly physicians have adopted it", Leite said. "But the reality is that only 30 percent to 50 percent of patients derive benefit from these drugs, while the rest really don't. So, the question becomes, who is likely to benefit, and if you're not benefiting, that is a missed opportunity to be on a therapy that could potentially give you a better outcome".

In addition to launching Dawn IO Melanoma, InterVenn said this week that it has started recruitment for a clinical registry of patients with advanced malignancies who are starting immune checkpoint inhibitor treatment. Participants will provide the company with a blood sample and clinical data tracking their diagnosis and treatment. InterVenn said the registry will "support current and future discovery" of products in its immunotherapy pipeline, which it has named its Dawn product line.

Tests for guiding immunotherapy have become the core of the company's commercial strategy, replacing an initial focus on cancer early detection. Leite said the company is working with a number of pharma partners who are exploring whether InterVenn's tests could help identify likely responders and non-responders.

"We are looking for partners who have IO therapies and are seeking stratification methods", he said. "Dawn will evolve as a companion diagnostic solution, and we rely on pharma partners to do that".

Leite said InterVenn still maintains an interest in developing tests for cancer screening. It is continuing work on its ovarian cancer diagnostic, Glori, which uses glycoprotein measurements to assess whether a pelvic mass is likely benign or malignant, and whether it should be removed by a gynecologist or a gynecologic oncologist. Leite said the company plans to ultimately commercialize that test by licensing it to an outside partner.

He added that the company is pursuing several other cancer screening tests and that it plans to make announcements regarding those efforts later this year.

InterVenn also announced this week that it has joined the Worldwide Innovative Network (WIN) Consortium and the Foundation for the National Institutes of Health's Biomarker Consortium and will bring its glycoproteomic-focused approach to biomarker discovery to both organizations.