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By Catherine Longworth

CHRONIX BIOMEDICAL INC. WILL START offering around a month from now its circulating cell-free tumour DNA-based test to monitor patients undergoing immunotherapy, following positive results from a study demonstrating the test's ability to predict therapeutic response to immunotherapy in multiple solid tumor types. Results from the study were published in the journal *Clinical Cancer Research* on Mar 20.

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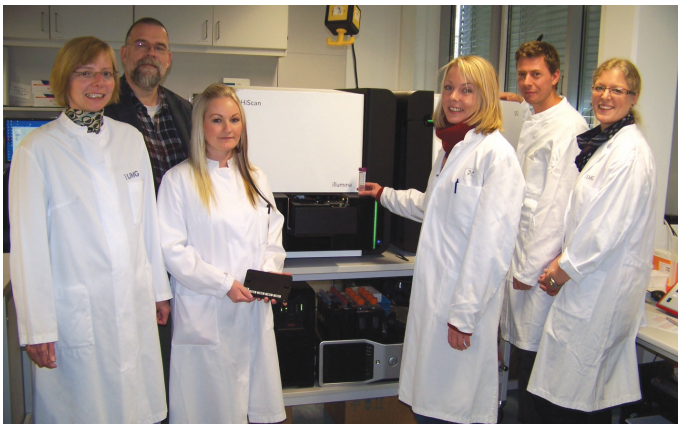
The liquid biopsy test uses proprietary algorithms to derive a copy number instability (CNI) score from sequencing circulating cell-free tumour DNA (cfDNA). Unlike conventional cancer molecular diagnostics, which seek to detect single mutations or rearrangements in the gene, Chronix's technology takes a more holistic approach by looking at the gains and losses of chromosomal regions in the genome – these gains and losses are representative of genomic instability caused by bad DNA repair and this can give an indication of how well a patient is recovering and their response to response to their cancer treatment.

"The study showed that our test has the ability to make an early prediction of response and disease control, just three to four weeks after initiation of immunotherapy," Chronix CEO, Howard Urnovitz, told *Medtech Insight*. "These results have great clinical implications. For the first time, doctors will have the flexibility to switch treatments early based on an accurate prediction and this has great potential to improve the treatment of many cancers."

The test has the potential to save healthcare providers on the high cost of immunotherapy drugs and any adverse side effects. The lab analysis -which will cost approximately €1,700 - will be available through a ISO 15189 lab that can accept samples from European countries permitting ISO labs to run tests. "Because of the publication of this paper, we can offer this as a laboratory-developed test in our ISO labs that will be opening in the next three to four weeks," said Urnovitz. "Doctors will be able to order analysis, it's not yet reimbursed so it will only be available through private medical insurers or by paying out of pocket until we can get reimbursement for all patients."

Chronix's blinded, prospective study was designed to validate its algorithm to calculate the CNI score and to predict response to treatment after one or two cycles of immunotherapy in a range of cancers. "The primary objective of the study was to find out if our blood test technology could predict clinical outcomes earlier than what is used currently in imaging, known as the RECIST (Response Evaluation Criteria in Solid Tumors) program," explained Urnovitz.

Blood samples were collected from 56 patients undergoing treatment with immunotherapy, mostly anti-PD1 immune checkpoint inhibitors with concurrent chemotherapy. Patients with 11 different tumour types including lung, kidney, breast, pancreatic, colorectal cancers and melanoma were assessed. Results from the study showed Chronix's test provided an 83% overall prediction accuracy in predicting response and disease progression, with a positive predictive value for progression of 92% after one cycle of immunotherapy. The findings showed that after a second cycle of immunotherapy, the CNI score yielded a 100% positive predictive value for progression.



Credit: Howard Urnovitz

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Six cases of hyper-progression were observed, five of which could be identified by CNI-score at six to nine weeks earlier than by the current practice of imaging. One patient with progressive disease who had been misclassified as stable on the basis of imaging assessments was also able to be identified by the CNI score.

Ekkehard Schütz, senior investigator on the study told *Medtech Insight*: "The problem that clinical colleagues who were treating patients were telling us was that they cannot really judge by other means whether the therapies were working or not, they can only see that after a couple of months of treatment and by imaging."

Urnovitz added: "The clinical implications of these results is it could lead to treating physicians to switch progressing or hyper-progressive patients to alternative therapies sooner and achieve better treatment outcomes, as identifying these patients through imaging or other methods can take several months. Furthermore, the fact the study showed accurate prediction of response and disease control with different cancers and with patients undergoing various treatments suggests the test should have broad applicability."

Chronix's test has also demonstrated feasibility as a predictor of therapeutic response to chemotherapy. The company presented an interim set of data from a blinded proof-of-concept study at the annual meeting of the American Association for Cancer Research (AACR) in 2016. *(Also see "Chronix's Liquid Biopsy Test Shows Promise In Predicting Therapeutic Response To Chemo" - Medtech Insight, 19 Apr, 2016.)*. Results of recently completed pilot studies in pancreatic cancer and head and neck cancer have also been submitted for presentation at a scientific meeting later this year.

Chronix intends to conduct a number of larger studies in individual cancers to validate the findings CNI-based testing in specific therapeutic monitoring applications and support regulatory submissions. The first such study in metastatic pancreatic cancer, where the standard assessment of treatment is particularly insufficient, is already well underway, the company stated.

Urnovitz said: "Because medical decisions being made with patients using our tests, we are going to take the 510(k) route with the US FDA. With the FDA program, we have to show equivalence to an already proven biomarker so we will be taking pancreatic cancer patients to compare to the proved biomarkers CA19-9 and show that our test is equivalent or better. From there, we hope to get FDA release which will help us get Medicare and other American insurers to reimburse."