Chronix Biomedical: Changes in Tumor Cell-Free DNA Copy Number Instability (CNI) Predict Therapeutic Response to Immunotherapy

Clinical data published today and to be presented at ASCO Annual Meeting 2016

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SAN JOSE, Calif. & GÖTTINGEN, Germany--(BUSINESS WIRE)--Chronix Biomedical, Inc., a developer of blood-based molecular diagnostics, today announces positive data from a blinded proof of concept clinical study, assessing the utility of tumor cell-free DNA ('cfDNA') as a predictor of therapeutic response to immunotherapy after the first cycle of treatment in eight different types of cancer.

"Tumor cell-free DNA copy number instability (CNI) predicts therapeutic response to immunotherapy prior to cycle 2"

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The abstract published today, *"Tumor cell-free DNA copy number instability (CNI) predicts therapeutic response to immunotherapy prior to cycle 2" (see link),* will be presented at the American Society of Clinical Oncology ('ASCO') Annual Meeting 2016 on 5 June 2016 at McCormick Place in Chicago, Illinois.

The abstract and poster presentation describe the work conducted by independent oncologists in a blinded study to evaluate Chronix Biomedical's genomic copy number instability score ('CNI') and its potential to predict a patient's response to immunotherapy.

The study was designed to assess CNI performance against RECIST 1.1 and irRECIST, medical standard of care for the assessment of treatment outcomes, and CNI's effectiveness in predicting treatment outcomes in multiple tumor types undergoing immunotherapy, or combined chemotherapy and immunotherapy treatment.

The study was conducted in 23 patients, one with stage 3 cancer; the rest with stage 4 cancer. Patients were stratified as partial-responders, stable disease or progressive disease to immunotherapy by RECIST1.1. CNI analysis correctly stratified patients with progressive disease and partial-responders in 88% (15 of 17 patients) of cases after the second cycle of immunotherapy treatment and 82% after the first cycle, demonstrating strong concordance. In this study, CNI was used in eight different tumor types (4 advanced melanoma (MEL), 2 renal cell carcinoma (RCC), 5 gastrointestinal, 4 pulmonary, 3 breast, 1 ovarian cancer, 3 pancreatic adenocarcinomas and 1 sarcoma – MEL and RCC received interleukin-2, while the rest received anti-PD-1 with chemotherapy).

Dr Nick Plowman, Senior Consultant Physician and Clinical Oncologist to St. Bartholomew Hospital and The Hospital for Sick Children, London, UK, and a scientific advisor to Chronix Biomedical, said:

"These highly encouraging results are supportive of changes of CNI being a useful tool for predicting patients' responses to immunotherapy. Performing such a simple blood test to quickly identify patients responding to therapy, and faster than is currently possible with serial imaging, would confer significant improvements to the provision of healthcare. Not only could clinicians quickly assess the response to the chosen therapy for the patient and ineffective treatments changed sooner, but also, in an age of limited healthcare resources, there are important healthcare economic arguments for such methodology."

Clinical data supporting the ability of CNI to predict therapeutic response to radiotherapy in patients with oropharyngeal cancers will also be published at ASCO. The significant findings of this blinded study were that cfDNA has an unexpectedly high sensitivity in even small head and neck cancers and that CNI has furthermore the potential to be a valuable addition to patient risk stratification and monitoring for relapse in this disease setting.

In addition to the clinical evidence published today, Chronix Biomedical presented data at the American Association for Cancer Research ('AACR') Annual Meeting 2016 last month, which was supportive of CNI as a predictor of therapeutic response to conventional cancer treatment. The study evaluated the ability of CNI to predict a patient's response to cytotoxic chemotherapy in five types of metastatic cancer. CNI analysis correctly stratified patients as either responders or non-responders to chemotherapy in 92% (22 of 24 patients) of cases when compared to RECIST, demonstrating strong concordance.

Combined, these studies demonstrate that CNI analysis is able to predict treatment outcomes and monitor for relapse in patients undergoing immunotherapy, chemotherapy and radiotherapy in different cancers, exhibiting broad clinical utility.

Chronix Biomedical's CEO, Dr Howard B. Urnovitz, commented:

"We are extremely encouraged to be able to add this important proof of concept study to our convincing body of clinical evidence supporting copy number instability as a monitoring test and early predictor of therapeutic outcomes to cancer treatments. Today's data, which are being presented at the prestigious ASCO annual meeting, demonstrate that CNI has the potential to differentiate responders from non-responders in eight different tumor types and can predict clinical outcome to immunotherapy with a simple blood draw earlier than by other standard measures. This builds on our recent success in chemotherapy and radiotherapy. These collective results give us the confidence to continue to expand our clinical data and progress the development of this important diagnostic tool, complementing our growing prostate cancer testing service, Second Opinion™."

About Chronix Biomedical

Chronix Biomedical, Inc. is a US-based molecular diagnostics company developing blood tests primarily for the screening and monitoring of cancer. Chronix already offers supplemental screening evaluation tests based on copy number instability for breast and prostate cancer through its own certified laboratories in Göttingen, Germany. The prostate cancer test can discriminate between prostate cancer and other prostate conditions (such as benign prostatic hypertrophy and prostatitis) thereby avoiding invasive needle biopsies when unnecessary. These Chronix supplementary tests assist oncologists in making cancer diagnoses and can reduce costs to healthcare providers by preventing unnecessary procedures such as tissue biopsies.

For more information visit www.chronixbiomedical.com.

Second Opinion™

Chronix Biomedical offers a testing service prostate cancer, known as Second Opinion™, through its own certified laboratories in Göttingen Germany. Second Opinion™ was launched following a 800 patient study including 200 prostate cancer patients, 200 breast cancer patients and 400 cancer-free matched samples. The Second Opinion™ Prostate Cancer Evaluation test can discriminate between prostate cancer and other prostate conditions (such as benign prostatic hypertrophy and prostatitis) thereby avoiding invasive needle biopsies when unnecessary. This supplementary evaluation test assists oncologists in making cancer diagnoses and can prevent unnecessary procedures such as tissue biopsies and unnecessary therapeutic intervention therefore reducing overall healthcare costs. The Company expects to offer a similar testing service for breast cancer later this year.

RECIST 1.1 and irRECIST

Response Evaluation Criteria In Solid Tumors “RECIST” is an internationally recognised voluntary standard used to assess solid tumor response to treatment. RECIST aims to define tumor response and identify a response, disease stabilisation or progression. Immune-related Response Evaluation Criteria In Solid Tumors “irRECIST” is specific to the assessment of the effect of immunotherapeutic agents.

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