

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

Poster presentation at American Association for Cancer Research 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 presents 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 chemotherapy in metastatic cancers, at the American Association for Cancer Research ('AACR') Annual Meeting 2016 held at the Ernest N. Morial Convention Center, New Orleans, Louisiana, USA.

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The poster presentation at AACR describes 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 cytotoxic chemotherapy.

The study was designed to assess CNI performance against RECIST 1.1, an industry standard for the assessment of treatment outcomes, and CNI's effectiveness in multiple tumor types. 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. Encouragingly, CNI also stratified patients in five different tumor types (lung cancer, non-Hodgkin lymphoma, pancreatic cancer, colorectal cancer and oesophageal cancer), demonstrating that this new test may have broad clinical utility.

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:

“A simple blood test, such as this, could reliably and quickly identify patients who will respond to chemotherapy. Clinicians could then make a more informed choice as to the most appropriate therapeutic option, while allowing healthcare providers to better allocate scarce healthcare resources.”

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

"We are pleased to be able to present encouraging data supportive of copy number instability as a predictor of chemotherapy treatment response at this prestigious scientific meeting. This initial data demonstrates that CNI has the potential to identify responders and non-responders in five different tumor types and predict response to chemotherapy earlier and less invasively than current methods. These results give us the confidence to continue to expand into other treatment modalities, additional cancers and larger studies as we build our clinical data and progress in the development of this important diagnostic tool."

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

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.

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