Chronix Biomedical: Study Results on Cell-Free DNA Test for Kidney Transplantation Presented at AACC - Product Launch in US in near Term

- *Results of prospective study using graft-derived circulating free DNA as biomarker for rejection in organ transplantation presented at the American Association of Clinical Chemistry (AACC) annual meeting*
- *Chronix test provides means to monitor patients for early signs of rejection*
- *Chronix will launch test in EU and USA*

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SAN JOSE, Calif. & GÖTTINGEN, Germany--(BUSINESS WIRE)--Chronix Biomedical, Inc., a developer of novel blood-based molecular diagnostics, reports that a review of clinical studies of its Therasure™ Transplant Monitor test for early signs of organ transplant rejection in solid organ transplantation was presented yesterday at the American Association of Clinical Chemistry (AACC) annual meeting.

The presentation was made in an oral session by Chronix's academic collaborator Dr. Michael Oellerich (MD, Hon MD, FAACC, FAMM, FFPath (RCPI), FRCPath) Professor of the University Medical Centre Goettingen, Germany and former president of WASPaLM. Dr Oellerich presented detailed results from a prospective study of Chronix's Therasure™ Transplant Monitor in kidney transplant recipients[1], and reviewed data from separate and previously published studies in liver and heart transplants.

Dr Oellerich asserted that the data shows that Therasure™ Transplant Monitor can be used successfully to achieve an early indication of rejection episodes and therefore would allow quick post transplant treatment modification to prevent organ damage.

Chronix's Therasure™ Transplant Monitor measures graft-derived cell-free DNA (GcfDNA) in blood, as a biomarker for early signs for acute rejection and organ health, which can avoid the need for patients to undergo unnecessary biopsies. Periodic monitoring via a blood test for signs of rejection post transplantation allows physicians to individually adjust levels of immunosuppression given to patients to avoid risk of full blown rejection. Unnecessary biopsies are performed frequently since conventional markers indicate the need for a biopsy when no biopsy is necessary. The Chronix test can avoid such unrequired biopsies. In addition the weakness in conventional markers is that they are not sensitive enough to detect subclinical but long lasting chronic rejections.

Chronix has now conducted multicentre studies of Therasure™ in more than 500 solid organ transplantation recipients, the results of which have been published in peer reviewed journals and presented at scientific conferences[2,3]. The work has been supported by grant funding from the German Federal Ministry of Education and Research.

One important finding indicated on the accompanying AACC poster presentation, is that the Chronix test quantifies an absolute amount of GcfDNA in the blood that is released by the transplanted organ[4]. This is significant because the absolute amount of GcfDNA in the blood of a transplant recipient is seen to be superior over the usually reported percentage value within the background cfDNA for rejection detection in kidney transplant. Therasure™ Transplant Monitor is the only product on the market that provides such quantification.

Dr Oellerich summarized: “The clinical benefit of GcfDNA determination for transplant recipients is now well established. The Therasure™ test we used in our studies, has a broad quantifiable range from 0.15% to 100%, which is superior to existing tests on the market, which is covered by Medicare with only 0.2% to 16%. In liver recipients higher values than 16% are very common in rejection so that such low linear range assays cannot be applied. In kidney transplantation, Therasure™ Transplant Monitor with the unique feature of absolute quantification is helpful to avoid unnecessary biopsies and has the potential to identify unrecognized under-immunosuppression in patients carrying the risk for de novo donor specific antibody formation leading to late graft loss.”

The data shows that Therasure™ has a broader applicability than competitor tests in terms of detecting early transplant rejection of all major solid organ transplants. The company is currently introducing it’s Therasure™ product line in European countries with a commercial partner laboratory and will enter the US market in the next 12 months.

Chronix Biomedical’s chief executive officer and chief medical officer Dr Ekkehard Schütz, M.D., Ph.D., FAACC commented: *“We are delighted that results from this prospective study were selected for oral presentation at the AACC. Our goal was to develop a test that serves the clinical need, so it should have a short turnaround time (1 day) and reasonable cost (below $600), to make serial determination during the course of a patient with a organ transplant affordable. In our experience, doctors seek a short turnaround time rather than having to wait a week for a test result to help them make a treatment decision. Both goals have been met, and now that our test has been launched in EU, we intend to offer our TheraSure™ TX-monitor through a CLIA lab and distributing labs in the US in the near term.”*

Mr. John DiPietro, CFO of Chronix stated: *“Physicians should certainly welcome the Chronix Therasure™ test that will be marketed at around a quarter of the Medicare reimbursement price of the tests currently available in the US. We expect Insurance companies to welcome a test that is broadly applicable to all transplants and less expensive to detect and monitor organ transplant rejection. We want to provide products that are affordable and accurate. We now have available in the marketplace the Chronix transplantation test for monitoring of patients receiving all major solid organ transplants such as heart, liver and kidney. Therasure™ Transplant Monitor should be very inviting to both physicians and insurance companies.”*

About Chronix Biomedical

Chronix Biomedical, Inc. is a US-based molecular diagnostics company developing blood tests for use in cancer treatment and organ transplantation. Chronix’s Therasure™ CNI Monitor for cancer uses proprietary algorithms to derive a copy number instability (CNI) score from sequencing of circulating cell-free tumour DNA (cfDNA), which can be used in the prognosis, diagnosis and monitoring of therapeutic response to cancer. Chronix Therasure™ Transplant Monitor quantifies the amount of graft derived cell-free DNA in organ recipients, to detect early rejection of organ transplants and better identify the transplant will be accepted. For more information visit: www.chronixbiomedical.com.

References

[1] Absolute quantification of graft-derived cell-free DNA as a marker of rejection and graft injury in kidney transplantation - results from a prospective observational trial (Oellerich *et al. AACC 2018).*

[2] Graft-derived cell-free DNA - a promising rejection marker in cardiac transplantation - Results from a prospective observational trial (Schütz *et al,* AACC Annual meeting eBook 2017: A-121).

[3] Graft-derived cell-free DNA, a non-invasive early rejection and graft damage marker in liver transplantation: A prospective, observational, multicenter cohort study (Schütz *et al*. Plos Medicine 2017), (see link)

[4] Absolute Quantification of Graft derived cell-free DNA (GcfDNA) early after Liver Transplantation (LTx) using droplet Digital PCR. (Beck J et al. Clin Chem,2014: suppl. Meeting Abstract B-215)

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