CIRCULOGENE

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**FOR IMMEDIATE RELEASE**
**DATE: June 17, 2019**

**CIRCULOGENE – Subcontractor to U.S. Department of Defense Research Award – to Develop Liquid Biopsy Markers for Traumatic Brain Injury**

*$1.5 Million grant to The Geneva Foundation will use CIRCULOGENE's liquid biopsy to quickly ID and accurately quantify organ-specific injury markers for improved treatment and survival in severely wounded military and civilian personnel*

**BIRMINGHAM, Ala.** – CIRCULOGENE molecular diagnostics laboratory, a subcontractor to The Geneva Foundation (Geneva), which has been awarded a $1.5 million U.S. Department of Defense grant, is to develop liquid biopsy markers for the rapid and accurate assessment of traumatic brain injury (TBI). The Defense Medical Research and Development Program (DMRDP) Precision Trauma Care Research Award (PTCRA) is to support research applying precision medicine concepts to trauma care.

"As one of the leading molecular diagnostics laboratories in the world, we are proud to have been selected as a partner for this project," said CIRCULOGENE CEO Mike Mullen. "This award recognizes our proprietary, in situ, cell-free DNA (cfDNA) quantification process, which will be key in helping researchers identify and measure circulating markers of TBI and other battlefield trauma."

TBI, alone and in combination with polytrauma and lung injury, causes the vast majority of combat-related deaths. In recent conflicts, more than 80 percent of wounded U.S. service members had some form of TBI complicated with trauma to the chest and bleeding, leading to severe combined injuries and acute lung failure.

"There are currently no viable treatment options for these patients due primarily to the severity of injury. Therefore, specific and accurate injury severity markers and diagnostic tools must be identified before effective therapeutic interventions are developed," said project principal investigator Andriy Batchinsky, M.D., a Geneva employee.

"Our proposal aims to address the unmet needs of combat trauma patients by using our micro-

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liquid biopsy platform to identify and quantify targeted indicators of injury severity and tissue-of-origin in cfDNA," explained CIRCULOGENE Chief Scientific Officer Chen-Hsiung Yeh, Ph.D.

Although plasma cfDNA of trauma patients has been investigated, a fast, efficient and accurate quantitation method to establish cfDNA as a sensitive biomarker for TBI remains a problem due to the limited quantity and fragmented nature of cfDNA in circulation. Standard DNA quantification methods are unreliable and suffer from significant DNA loss during extraction.

CIRCULOGENE's linear in situ amplification (LISA) technology combines loss-free with linear cfDNA quantification, resulting in unprecedented accuracy, which is perfectly suited to the current challenge. In the current study, researchers will use animal models with combat-relevant trauma and look for special injury severity markers including cfDNA in the blood. Ultimately, leading to the quickest and most effective intervention.

Another ambitious goal of the grant is to establish and analyze specific cfDNA organ damage signatures using LISA for early battlefield patient triage and effective treatment. With TBI markers and the addition of polytrauma and lung injury testing, researchers hope to improve diagnosis and provide targeted therapeutic intervention through extracorporeal life support (ECLS) devices. The innovative tissue-tracking technology will have broad applications beyond TBI, for example, in the early detection of disease in oncology, cardiovascular disease, diabetes and obesity.

This work is supported by the Office of the Assistant Secretary of Defense for Health Affairs through the Defense Medical Research and Development Program (DMRDP) under Award Number W81XWH-19-2-0008. Opinions, interpretations, conclusions and recommendations are those of the author and are not necessarily endorsed by the Department of Defense.

CIRCULOGENE is Clinical Laboratory Improvement Amendments (CLIA) and College of American Pathologists (CAP) certified and provides biomarker testing for a broad range of cancers, allowing physicians to match results to specific drugs and clinical trials in just one

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week. Using a single tube of blood (4 mL), CIRCULOGENE is able to test for circulating genetic mutations and tumor biomarkers among DNA mutations, RNA fusions, PD-L1 expression and MSI. NTRK testing, as previously announced, will be added to the testing menu in the immediate future.

For more information, visit our website, connect with us on LinkedIn, Facebook and Twitter, or email us at info@circulogene.com or call 855-614-7083. Clinicians interested in ordering tests may visit the Contact page on CIRCULOGENE's website.

**About CIRCULOGENE**

*Headquartered in Birmingham, Ala., CIRCULOGENE is an innovative molecular diagnostics company founded and operated by a team of experienced industry executives and skilled molecular diagnostics scientists. Applying its proprietary laboratory developed test for cfDNA, cfRNA and MSI liquid biopsies, CIRCULOGENE has developed a next-generation sequencing (NGS) method to provide full genomic load analysis from one standard tube of blood in one week, enabling more accurate data to help clinicians and their patients choose targeted therapies, monitor efficacy and monitor for recurrence. One tube, one week, complete results. Somatic + Germline; Blood + Tissue + Buccal; DNA + RNA + MSI + PD-L1. For more information, visit www.circulogene.com or call 855-614-7083.*

**About The Geneva Foundation**

*The Geneva Foundation is a 501(c)3 non-profit organization that advances military medicine through innovative scientific research, exceptional program management, and a dedication to U.S. service members and veterans, their families, and the global community. Geneva is proud to have over 25 years of experience in delivering full spectrum scientific, technical, and program management expertise in the areas of federal grants, federal contracts, industry sponsored clinical trials, and educational services. www.genevaUSA.org*

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