

# CytoSorbents Awarded Approximately \$650,000 in SBIR Funding to Continue Development of Novel Hemocompatible Potassium Binding Polymers

Promising therapy is designed to provide much-needed rapid treatment of life-threatening hyperkalemia in critically-injured patients

MONMOUTH JUNCTION, NJ — August 8, 2016 - CytoSorbents Corporation (NASDAQ: CTSO), a critical care immunotherapy company specializing in the purification of blood and bodily fluids, announced the award of approximately \$650,000 in SBIR program funding. The company was awarded a \$492,951 Phase II Enhancement from the U.S. Army Small Business Innovation Research (SBIR) Program. In addition, the company also announced a new Defense Health Agency Phase I SBIR Program award in the amount of \$149,927. Both awards are managed by the U.S. Army Medical Research and Materiel Command (USAMRMC) and are intended to fund continued development of novel hemocompatible potassium binding polymers and substrates that can rapidly treat life-threatening hyperkalemia in critically-injured warfighters, civilian patients, and patients with impaired kidney function, such as dialysis patients.

"These potassium binding polymers represent an entirely new product category for the company. They leverage the massive surface area of our existing hemocompatible porous polymers with robust potassium binding technology to target rapid and sustained potassium reduction without the need for complicated dialysis," said Dr. Phillip Chan, MD, PhD, Chief Executive Officer of CytoSorbents. "Our goal is to provide field medics with easy-to-administer solutions to acutely treat and stabilize wounded warfighters suffering from severe hyperkalemia as a result of massive trauma, burn injury, kidney failure, blood transfusions, and other conditions. These strategies could enable prolonged field care, particularly in far-forward situations where rapid evacuation is neither safe nor feasible. As a simpler, more rapid, and logistically friendly alternative to dialysis, we also envision our technology being used in emergency room or hospitalized patients with severe hyperkalemia, and helping victims of bombings, earthquakes, landslides and other mass casualty situations."

Hyperkalemia is defined as the excessive concentration of potassium in the blood. Potassium is an important electrolyte in the body that is present inside cells at high concentrations, with the amount in blood tightly regulated. Following injury to cells by, for example, trauma, burn

injury, ischemia, or cytotoxic drugs, such cells will continuously leak high levels of potassium into the blood, resulting in hyperkalemia. The kidneys normally excrete excess potassium from the blood, but when compromised, as in critically-ill patients suffering from kidney failure or in chronic dialysis patients with end-stage kidney disease, the levels of blood potassium can rapidly rise unabated. When the potassium level in the blood exceeds a concentration of 6.0 mmol/L (normal 3.6 - 5.2 mmol/L), the risk of heart arrhythmias and sudden cardiac death increases significantly. Orally administered potassium sorbents such as Kayexalate® (Sanofi-Aventis) and Veltassa® (Relypsa) are only recommended for the non-emergent lowering of mild to moderate hyperkalemia, while the use of insulin and glucose to drive potassium into cells in severe hyperkalemia is only a temporary strategy. Dialysis has been the definitive treatment of severe hyperkalemia, but requires a large dialysis machine, an electrical wall socket, bags of dialysate, a skilled technician, and prolonged treatment times that are not practical in certain situations such as far-forward or remote areas. CytoSorbents is collaborating with leading military researchers to optimize prototype polymers capable of rapidly reducing serum potassium in large animal models, using simple "blood in, blood out" hemoperfusion systems and other strategies.

Hyperkalemia is a common problem and has been reported to occur in 1.7-5.2% of hospitalized patients in a number of studies. It has also been recognized as a serious complication of combat injury since World War II, when hyperkalemia and acute kidney injury was associated with a mortality rate of 90%, and was a leading cause of post-traumatic death in the Korean War, until the advent of dialysis therapy. In the wars in Iraq and Afghanistan, an estimated 5.8% of all combat casualties developed hyperkalemia within 48 hours of injury. Even in noncrush traumatic injury, severe hyperkalemia (>6 mmol/L) occurred in approximately 20% of patients. Hyperkalemia was also observed in approximately 16% of victims of natural disasters such as earthquakes, where crush injury is common. Because of this, there is a significant worldwide need for an easy-to-administer but effective treatment of severe hyperkalemia. Literature references are available upon request.

Funding is managed by USAMRMC under a recently awarded \$492,951 Phase II Enhancement increasing the previous U.S. Army SBIR Phase I and II program funding on this effort, under Contract No. W81XWH-12-C-0038. In addition, CytoSorbents was awarded a new Defense Health Agency SBIR Phase I contract totaling \$149,927 under Contract No. W81XWH-16-C-0080. Upon successful completion of the Phase I effort, the company will be positioned for competitive selection in the Phase II SBIR program, valued at up to one million dollars.

The views, opinion and/or findings contained in this press release are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation. In conducting research using animals, the investigator(s) adhered to the Animal Welfare Act Regulations and other Federal statutes relating to animals and experiments involving animals and the principles set forth in the current version of the Guide of Care and Use of Laboratory Animals, National Research Council.

## **About CytoSorbents Corporation (NASDAQ: CTSO)**

CytoSorbents Corporation is a leader in critical care immunotherapy, specializing in blood purification. Its flagship product, CytoSorb® is approved in the European Union with distribution in 37 countries around the world, as a safe and effective extracorporeal cytokine adsorber, designed to reduce the "cytokine storm" or "cytokine release syndrome" that could otherwise cause massive inflammation, organ failure and death in common critical illnesses such as sepsis, burn injury, trauma, lung injury and pancreatitis, as well as in cancer immunotherapy. These are conditions where the risk of death is extremely high, yet no effective treatments exist. CytoSorb® is also being used during and after cardiac surgery to remove inflammatory mediators, such as cytokines and free hemoglobin, which can lead to post-operative complications, including multiple organ failure. CytoSorbents is currently conducting its REFRESH (REduction in FREe Hemoglobin) 1 trial - a multi-center, randomized controlled study evaluating the safety of intra-operative CytoSorb® use in a heart-lung machine during complex cardiac surgery. In early 2017, the company plans to initiate a pivotal REFRESH 2 trial intended to support U.S. FDA approval. CytoSorb® has been used safely in more than 12,000 human treatments to date.

CytoSorbents' purification technologies are based on biocompatible, highly porous polymer beads that can actively remove toxic substances from blood and other bodily fluids by pore capture and surface adsorption. Its technologies have received non-dilutive grant and contract funding well in excess of \$17 million from DARPA, the U.S. Army, the U.S. Air Force, the Defense Health Agency, the National Institutes of Health, and others. The Company has numerous products under development based upon this unique blood purification technology, protected by 32 issued U.S. patents and multiple applications pending, including HemoDefend™, ContrastSorb, DrugSorb and others. For more information, please visit the Company's websites: <a href="http://www.cytosorbents.com">http://www.cytosorbents.com</a> and <a href="http://www.cytosorbents.com">http://www.cytosorb.com</a> or follow us on <a href="facebook">Facebook</a> and <a href="mailto:Twitter">Twitter</a>

# **Forward-Looking Statements**

This press release includes forward-looking statements intended to qualify for the safe harbor from liability established by the Private Securities Litigation Reform Act of 1995. These forwardlooking statements include, but are not limited to, statements about our plans, objectives, representations and contentions and are not historical facts and typically are identified by use of terms such as "may," "should," "could," "expect," "plan," "anticipate," "believe," "estimate," "predict," "potential," "continue" and similar words, although some forward-looking statements are expressed differently. You should be aware that the forward-looking statements in this press release represent management's current judgment and expectations, but our actual results, events and performance could differ materially from those in the forwardlooking statements. Factors which could cause or contribute to such differences include, but are not limited to, the risks discussed in our Annual Report on Form 10-K, filed with the SEC on March 9, 2016, as updated by the risks reported in our Quarterly Reports on Form 10-Q, and in the press releases and other communications to shareholders issued by us from time to time which attempt to advise interested parties of the risks and factors which may affect our business. We caution you not to place undue reliance upon any such forward-looking statements. We undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise, other than as required under the Federal securities laws.

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