Groundbreaking Randomized Controlled Trial Reports Excellent Clinical Outcomes Using CytoSorb® Intraoperatively in Heart Transplant Patients

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CytoSorb Blood Purification Results in Statistically Significant Reductions in Multiple Organ Failure and Dysfunction

PRINCETON, N.J., Jan. 17, 2024 (GLOBE NEWSWIRE) -- CytoSorbents Corporation (NASDAQ: CTSO), a leader in the treatment of life-threatening conditions in the intensive care unit and cardiac surgery using blood purification via its proprietary polymer adsorption technology, reports on excellent outcomes from a groundbreaking randomized controlled trial (RCT) using CytoSorb® blood purification during heart transplant, recently published in the European Society of Cardiology journal, ESC Heart Failure.

As co-lead authors Drs. Endre Németh and Adam Soltesz from the Heart and Vascular Center at Semmelweis University, Budapest, Hungary explain, as more complex and higher risk patients become eligible for heart transplant, so does the risk of serious complications such as multiple organ failure, that not only is the second leading cause of death following heart transplant, but results in high costs due to protracted ICU and hospital stays. In particular, vasoplegic syndrome (VS), a form of circulatory failure or shock, is routinely seen in these patients and can cause worsened organ failure. In a prior observational study, CytoSorb was associated with the reduced severity of vasoplegia in heart transplant patients, in addition to other clinical benefits.

In this prospective, single-center, open-label RCT, 60 heart transplant recipients were randomly assigned to either receive intraoperative CytoSorb hemoadsorption or standard of care. Key statistically significant findings of the study were that the CytoSorb group, compared to the control group, had:

1. **Better hemodynamic stability and lower rates of post-operative shock**
   - Patients in the CytoSorb group had lower median Vasoactive-Inotropic Scores (27.2 [14.6–47.7] vs. 41.9 [22.4–63.2], *p*=0.046) and Vasoplegic Syndrome rates (20.0% vs 48.0% control, *p*=0.028)
   - The odds of early Vasoplegic Syndrome were 6.4 times lower in the CytoSorb group (*p*=0.029).
2. **Shorter median time on mechanical ventilation**
   - 25 [19–68.8] hours vs. 65 [23–287] hours in control, *p*=0.025
3. **Lower rates of acute kidney injury (AKI) and need for renal replacement therapy (RRT)**
   - AKI: 36.7% vs. 76.0% control, *p*=0.004
   - Renal replacement therapy: 0% vs. 16.0% control, *p*=0.037
4. **Shorter median time in the ICU**
   - 8.5 [8.0–10.3] days vs. 12 [8.5–18.0] days in control, *p*=0.022
5. **No relevant removal of the anti-rejection drug mycophenolic acid (MPA)**
6. **Similar rates of cardiac allograft rejection, 30-day mortality, and 1-year survival between groups**
7. **There were no reported device-related adverse events during the study period**

Dr. Daniel Wendt, Vice President Medical – Cardiovascular at CytoSorbents stated, "Over the years, cardiothoracic surgeons have repeatedly observed the benefits of intraoperative CytoSorb blood purification in improved hemodynamic stability, reduced incidence and severity of vasoplegic shock, decreased incidence of organ dysfunction, reduced inflammatory responses, and favorable post-operative outcomes. Now, Nemeth, Soltesz, and colleagues have confirmed many of these observations in this rigorous and well-designed groundbreaking randomized controlled trial in orthotopic heart transplant patients. These vital and statistically significant clinical outcomes highlight the critical importance of CytoSorb in cardiothoracic surgery and are expected to be a catalyst for continued adoption, usage, and reimbursement in this arena. Also, on the heels of recent positive data in lung transplant using CytoSorb, these results continue to advance our pioneering role in the field of solid organ transplant in general."

About CytoSorbents Corporation (NASDAQ: CTSO)

CytoSorbents Corporation is a leader in the treatment of life-threatening conditions in the intensive care unit and in cardiac surgery through blood purification. Its lead product, CytoSorb®, is approved in the European Union and distributed in 75 countries worldwide. It is an extracorporeal cytokine adsorber that reduces “cytokine storm” or “cytokine release syndrome” in common critical illnesses that can lead to massive inflammation, organ failure and patient death. In these diseases, the risk of death can be extremely high, and there are few, if any, effective treatments. CytoSorb is also used during and after cardiothoracic surgery to remove antithrombotic drugs and inflammatory mediators that can lead to postoperative complications, including severe bleeding and multiple organ failure. At the end of Q3 2023, more than 221,000 CytoSorb devices had been used cumulatively. CytoSorb was originally launched in the European Union under CE mark as the first cytokine adsorber. Additional CE mark extensions were granted for bilirubin and myoglobin removal in clinical conditions such as liver disease and trauma, respectively, and for ticagrelor and rivaroxaban removal in cardiothoracic surgery procedures. CytoSorb has also received FDA Emergency Use Authorization in the United States for use in adult critically ill COVID-19 patients with impending or confirmed respiratory failure. The DrugSorb™-ATR antithrombotic removal system, based on the same polymer technology as CytoSorb, also received two FDA Breakthrough Device Designations, one for the removal of ticagrelor and another for the removal of the direct oral anticoagulants (DOAC) apixaban and rivaroxaban in a cardiopulmonary bypass circuit during urgent cardiothoracic procedures. The Company has completed the FDA-approved, randomized, controlled STAR-T (Safe and Timely Antithrombotic Removal-Ticagrelor) study of 140 patients at approximately 30 centers in U.S. and Canada to evaluate whether intraoperative use of DrugSorb-ATR can reduce the perioperative risk of bleeding in patients receiving ticagrelor and undergoing cardiothoracic surgery. This pivotal study is intended to support U.S. FDA and Health Canada marketing approval for DrugSorb-ATR in this application.

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, contract, and other funding of approximately $50 million from DARPA, the U.S. Department of Health and Human Services (HHS), the National Institutes of Health (NIH), National Heart, Lung, and Blood Institute (NHLBI), the U.S. Army, the U.S. Air Force, U.S. Special Operations Command (SOCOM), Air Force Material Command (USAF/AFMC), and others. The Company has numerous marketed products and products under development based upon this unique blood purification technology protected by many issued U.S. and international patents and registered trademarks, and multiple patent applications pending, including ECOS-300CY®, CytoSorb-XL™, HemoDefend-RBC™, HemoDefend-BGA™, VetRes®, K+ontrol™, DrugSorb™, ContrastSorb and others. For more information, please visit the Company's websites at www.cytosorbents.com and www.cytosorb.com or follow us on Facebook and X (fka Twitter).

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 forward-looking statements include, but are not limited to, statements about our plans, objectives, future targets and outlooks for our business, statements about potential exposures resulting from our cash positions, 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 forward-looking 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, 2023, 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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U.S. Company Contact:
Kathleen Bloch, CFO
305 College Road East
Princeton, NJ 08540
+1 (732) 398-5429

kbloch@cytosorbents.com

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