



### **Press Release**

## Biocon Expands its Strategic Partnership with CytoSorbents for CytoSorb® to Treat SIRS and Cardiac Surgery Patients

### Bangalore, India and Monmouth Junction, N.J., November 3, 2014 –

Biocon Ltd (BSE code: 532523, NSE: BIOCON), Asia's premier biopharmaceuticals company, and U.S.-based CytoSorbents Corporation (OTCQB: CTSO) announced today that they have expanded the scope of their strategic partnership for CytoSorbents' CytoSorb® cytokine reduction therapy to treat patients experiencing severe whole body inflammation, often called a Systemic Inflammatory Response Syndrome (SIRS). SIRS is caused by a wide range of life-threatening conditions seen in the intensive care unit and can also be caused by surgical interventions, particularly cardiac surgery.

Biocon will now have the exclusive, region-wide rights to distribute CytoSorb<sup>®</sup> for all critical care applications in the intensive care unit (ICU) as well as cardiac surgery applications for India and select emerging countries. As part of the expanded agreement, Biocon will also play a prominent leadership role in the generation of new clinical evidence to support the adoption and usage of CytoSorb<sup>®</sup>. This includes commitments to conduct and publish results from multiple Investigator Initiated Trials (IITs) and patient case studies.

So far, the response to CytoSorb<sup>®</sup> for the management of sepsis has been very encouraging with hundreds of patients in India having benefitted from this novel therapy. The expanded usage of CytoSorb<sup>®</sup> in other applications could improve patient outcomes and save precious lives.

**Mr Ravindra Limaye, President, Marketing, Biocon,** said: "CytoSorb® has been embraced by physicians as a safe and well-tolerated therapy for managing sepsis in critically-ill patients. Our expanded partnership with CytoSorbents will now enable us to address the huge unmet needs of patients experiencing a Systemic Inflammatory Response Syndrome (SIRS) as a result of burns, lung injury, liver failure, pancreatitis, post-cardiac surgery complications, and tropical diseases like malaria and dengue fever."

**Dr Abhijit Barve, President, Research & Development, Biocon**, said: "While our initial focus has been on sepsis, physicians are increasingly identifying conditions where very high levels of cytokines are known to cause multiple organ failure. We also believe there is a significant unmet

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medical need to manage high risk patients undergoing cardiac surgery by using CytoSorb<sup>®</sup> to control inflammation. We are excited about working together with CytoSorbents and look forward to playing an important role in advancing the clinical development of this product."

**Dr.** *Phillip Chan, Chief Executive Officer and President, CytoSorbents,* stated: "We are very pleased to expand our relationship with Biocon, which has been an exceptional partner in launching CytoSorb® in India. We take deep pride in the opportunity to potentially help more people in this part of the world by addressing a broader array of conditions. Moreover, Biocon is a world-class clinical development organization with strong capabilities in advancing new therapies. We look forward to working closely with Biocon as they generate clinical evidence to support the widespread use of CytoSorb®."

*Mr. Chris Cramer, Vice President of Business Development, CytoSorbents* said: "Biocon's results to date have been truly impressive and we are confident in their ability to lead the market development of CytoSorb<sup>®</sup> in this region. We are pleased to see Biocon making investments to establish a solid foundation for ongoing and sustainable growth that will benefit CytoSorb<sup>®</sup> commercialization not only in India, but throughout the world."

Financial terms of the agreement were not disclosed.

### **Biocon and Critical Care in India**

Biocon partnered with CytoSorbents in 2013 to launch CytoSorb<sup>®</sup>, a 'first-in-class' therapy to enable physicians to treat sepsis, the overactive immune response to a serious infection. Over the past year, Biocon has created a dedicated sales force that is solely focused on promoting CytoSorb<sup>®</sup> across multiple cities in India. CytoSorb<sup>®</sup>, an extracorporeal cytokine filter, has been enthusiastically embraced by physicians as a safe and well–tolerated therapy for managing sepsis in critically-ill patients. By reducing toxic levels of cytokines, CytoSorb<sup>®</sup> targets the modulation of the body's excessive immune response and the prevention or treatment of organ failure, the cause of nearly half of all deaths in the ICU.

The combination of Biocon's critical care antibiotics with CytoSorb<sup>®</sup> treatment during sepsis has benefitted hundreds of patients in India. Biocon's network of specialized sales force personnel is enabling rapid access, education, training, and support to physicians in large hospitals throughout India and other emerging markets. It has spearheaded several initiatives between Key Opinion Leaders (KOLs) and Specialists to help Intensivists understand the array of indications for which CytoSorb<sup>®</sup> therapy can be initiated to benefit a larger number of critically-ill patients.

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Additionally, Inflammation generated during cardiac surgery and cardiopulmonary bypass can lead to post-operative inflammation and adverse outcomes, including lung and kidney failure. The use of CytoSorb<sup>®</sup> intra-operatively in a bypass circuit in the heart-lung machine is designed to remove inflammatory substances and reduce post-operative complications. Under the expanded partnership, Biocon will leverage its cardiac care commercial capabilities to now promote CytoSorb<sup>®</sup> for treating harmful, excess inflammation associated with cardiac surgery.

**Severe sepsis** and septic shock are major causes of morbidity and mortality worldwide. It is a leading cause of death in non-coronary ICUs and the 11th leading cause of death overall. Over a third of patients who develop sepsis die globally, even when the best standard of care is available. In India, more than one million estimated new cases of severe sepsis are treated in the Indian ICUs each year, accounting for one out of every four patients in the ICU. According to a recent nationwide study of Indian Intensive Care Case Mix and Practice Patterns (INDICAPS) involving over 124 ICUs across 17 states in India, mortality was found to be as high as 46% in patients with septic shock and 42.2% overall in septic patients, compared with 17.8% mortality for ICU patients who did not develop sepsis.

According to the World Health Organization (WHO), **cardiovascular diseases** (CVD) are the top noncommunicable cause of death in India. Various factors are contributing to the higher prevalence of cardiovascular disease in India with risk factors such as hypertension, obesity, diabetes, and tobacco use on the rise. CVD is now more prevalent in India and China than in all economically developed countries in the world added together. In India alone, it is estimated that 2.5 Million patients are in need of heart surgery.

### About Biocon

Biocon Limited, publicly listed in 2004, (BSE code: 532523, NSE Id: BIOCON, ISIN Id: INE376G01013) is India's largest and fully-integrated, innovation-led biopharmaceutical company. As an emerging global biopharmaceutical enterprise serving customers in over 85 countries, it is committed to reduce therapy costs of chronic diseases like autoimmune, diabetes, and cancer. Through innovative products and research services it is enabling access to affordable healthcare for patients, partners and healthcare systems across the globe. It has successfully developed and taken a range of novel biologics, biosimilars, differentiated small molecules and affordable recombinant human insulin and analogs from 'Lab to Market'. Some of its key brands are INSUGEN®(rh-insulin), BASALOG® (Glargine), CANMAb™ (Trastuzumab), BIOMAb-EGFR™ (Nimotuzumab) and ALZUMAb ™(Itolizumab), a 'first in class' anti-CD6 monoclonal antibody. It has a rich pipeline of biosimilars and novel biologics at various stages of development including a high potential oral insulin. *For more:* www.biocon.com

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### About CytoSorbents Corporation

CytoSorbents Corporation (OTCBB: CTSO) is a critical care immunotherapy company using blood purification to modulate the immune system and fight multi-organ failure in life-threatening illnesses. Its purification technology is based on biocompatible, highly porous polymer beads that can actively remove toxic substances from blood and other bodily fluids by pore capture and adsorption. CytoSorb®, the Company's flagship product, is approved in the European Union as a safe and effective extracorporeal cytokine filter, designed to reduce the "cytokine storm" that could otherwise cause massive inflammation, organ failure and death in common critical illnesses such as sepsis, burn injury, trauma, lung injury, and pancreatitis. These are conditions where the mortality is extremely high, yet no effective treatments exist. CytoSorb® is also being used during and after cardiac surgery to try to remove inflammatory mediators, such as cytokines and free hemoglobin, which can lead to post-operative complications, including multiple organ failure. *For more visit our website*: www.cytosorbents.com

**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. Forward-looking statements in this press release are not promises or guarantees and are subject to risks and uncertainties that could cause our actual results to differ materially from those anticipated, including the acceptance of CytoSorb® by physicians in India and select emerging markets, and other factors. These statements are based on management's current expectations and assumptions and are naturally subject to uncertainty and changes in circumstances. We caution you not to place undue reliance upon any such forward-looking statements. Actual results may differ materially from those expressed or implied by the statements herein. Risk factors are detailed in the CytoSorbents' Form 10-K filed with the SEC on March 31, 2014, which is available at http://www.sec.gov.

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