MORRISVILLE, N.C.--(BUSINESS WIRE)--Oxygen Biotherapeutics, Inc. (OXBT) a specialty pharmaceutical company focused on developing and commercializing a portfolio of products for the critical care market, today announced a collaboration with Imperial College London to provide supplemental funding to support the accelerated enrollment and completion of the ongoing LeoPARDS Trial (Levosimendan for the Prevention of Acute oRgan Dysfunction in Sepsis) awarded by the Efficacy and Mechanism Evaluation (EME) Programme and funded by the Medical Research Council (MRC) and managed by the National Institute for Health Research (NIHR) on behalf of the MRC-NIHR partnership. Oxygen is also currently preparing to initiate a Phase 3 trial in the United States during the third quarter to evaluate levosimendan in cardiac surgery patients at risk of developing low cardiac output syndrome (LCOS).

The LeoPARDS trial is designed to determine whether levosimendan reduces the incidence and severity of acute organ dysfunction in adult patients who have septic shock, as well as evaluate its safety profile. Septic shock represents an area of very high unmet medical need, as the condition is associated with high mortality, morbidity and critical care costs. Given the limited treatment options that exist and the prior research data regarding the potential benefits of levosimendan in septic shock patients, the EME Programme awarded funding of the LeoPARDS trial, which will be led by Imperial College London.

“Early preclinical and clinical studies of levosimendan have demonstrated potentially unique beneficial effects on heart performance and organ perfusion in patients suffering from septic shock, with a differentiated mechanism that could avoid the pitfalls of commonly used adrenaline-like drugs,” said Dr. Anthony Gordon, chief investigator of the LeoPARDS trial and a critical care physician and septic shock expert at Imperial College London. “We are grateful to have the additional support from Oxygen Biotherpaeutics, a leader in the continued development of levosimendan, to help us accelerate trial enrollment as we work toward providing these patients with additional therapeutic options.”

“We are very pleased to support the LeoPARDS trial and to accelerate the timeline for results from this important study in septic shock patients,” said John Kelley, CEO of Oxygen Biotherapeutics. “Past clinical trials indicate that levosimendan may offer septic shock patients important clinical benefits, and our collaboration with Imperial College London on this trial is just one example of how we intend to utilize the significant European clinical experience with levosimendan across a wide range of critical care conditions to guide our development strategy in the United States. While our focus remains on our upcoming Phase 3 trial in cardiac surgery patients at risk of developing LCOS, we are currently monitoring a number of ongoing trials that are designed to evaluate levosimendan in indications such as high risk non-cardiac surgery, acute kidney injury, and acute respiratory failure, which could all represent attractive areas for further development to help patients with critical care conditions of high unmet need.”

The LeoPARDS trial began patient enrollment in the first quarter of 2014 with significant interest and trial enrollment, but the existing funding meant several interested clinical trial sites were unable to participate. Oxygen has agreed to provide supplemental funding of $500,000 through an unrestricted grant, which will allow additional sites to enroll patients more quickly.

The randomized, double-blind, placebo-controlled, multi-centre trial design is based on previously conducted small clinical trials which indicate that levosimendan may provide unique and important clinical benefits to septic shock patients through improved heart function and organ perfusion. The study protocol for this 500-plus patient trial was recently published and is available at: http://www.trialsjournal.com/content/15/1/199

About Levosimendan

Levosimendan is a calcium sensitizer developed for intravenous use in hospitalized patients with acutely decompensated heart failure. It was discovered and developed by Orion Pharma, Orion Corporation of Espoo Finland, and is currently approved in over 50 countries for this indication and not available in the United States. Oxygen Biotherapeutics recently acquired the North American rights to develop and commercialize levosimendan from Phyxius Pharma. The United States Food and Drug Administration (FDA) has granted Fast Track status for levosimendan for the reduction of morbidity and mortality in cardiac surgery patients at risk for developing Low Cardiac Output Syndrome (LCOS). In addition, the FDA has agreed to the Phase 3 protocol design under Special Protocol Assessment (SPA), and provided guidance that a single successful trial will be sufficient to support approval of levosimendan in this indication.

About LeoPARDS Trial

Sepsis is a life-threatening condition that causes the blood pressure to fall dangerously, compromising blood flow to vital organs such as the liver and kidney. It is the leading cause for admission to an intensive care unit in the UK, accounting for about 30% of all admissions. Despite advances in treatment around 40% of such patients unfortunately die.

Conventionally, adrenaline-like drugs are used to support a patient's blood pressure but they can have serious side effects. Levosimendan is a new type of drug that is currently used to treat patients with advanced heart failure. It works in a different manner to adrenaline-like drugs, potentially avoiding some of these side effects. It may also improve the blood flow to vital organs. In small scale clinical trials in patients with sepsis who have been given levosimendan significant improvements were seen in the function of the heart, kidneys and other organs.

This trial is designed to investigate whether giving levosimendan to ICU patients suffering from sepsis can improve the function of different organ systems and potentially improve the outcome for sepsis patients

About NHS and the National Institute for Health Research

1. The Efficacy and Mechanism Evaluation Programme supports later-phase "science-driven" clinical trials and evaluative studies, which seek to determine whether a health intervention (e.g. a drug, diagnostic technique or device) works and in some cases how or why it works.

2. The Efficacy and Mechanism Evaluation Programme (www.nets.nihr.ac.uk/programmes/eme) is funded by the MRC and NIHR, with contributions from the CSO in Scotland, NISCHR in Wales and the HSC R&D Division, Public Health Agency in Northern Ireland. It is managed by the NIHR Evaluation, Trials and Studies Coordinating Centre (NETSCC) based at the University of Southampton.

3. The National Institute for Health Research (NIHR) is funded by the Department of Health to improve the health and wealth of the nation through research. Since its establishment in April 2006, the NIHR has transformed research in the NHS. It has increased the volume of applied health research for the benefit of patients and the public, driven faster translation of basic science discoveries into tangible benefits for patients and the economy, and developed and supported the people who conduct and contribute to applied health research. The NIHR plays a key role in the Government's strategy for economic growth, attracting investment by the life-sciences industries through its world-class infrastructure for health research. Together, the NIHR people, programmes, centres of excellence and systems represent the most integrated health research system in the world. For further information, visit the NIHR website (www.nihr.ac.uk).

4. The Medical Research Council has been at the forefront of scientific discovery to improve human health. Founded in 1913 to tackle tuberculosis, the MRC now invests taxpayers' money in some of the best medical research in the world across every area of health. Twenty-nine MRC-funded researchers have won Nobel prizes in a wide range of disciplines, and MRC scientists have been behind such diverse discoveries as vitamins, the structure of DNA and the link between smoking and cancer, as well as achievements such as pioneering the use of randomised controlled trials, the invention of MRI scanning, and the development of a group of antibodies used in the making of some of the most successful drugs ever developed. Today, MRC-funded scientists tackle some of the greatest health problems facing humanity in the 21st century, from the rising tide of chronic diseases associated with ageing to the threats posed by rapidly mutating micro-organisms. www.mrc.ac.uk

This article presents independent research funded by the National Institute for Health Research (NIHR). The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health.

The National Health Service (NHS) is the publicly funded healthcare system for England. It is the largest and the oldest
single-payer healthcare
system in the world. Primarily funded through the general taxation system, the system provides healthcare to every legal resident in the United Kingdom, with most services free at the point of use.

About Oxygen Biotherapeutics

Oxygen Biotherapeutics, Inc. is a specialty pharmaceutical company focused on developing and commercializing a portfolio of products for the critical care market. The company recently acquired the North American rights to develop and commercialize levosimendan, and the United States Food and Drug Administration (FDA) has granted Fast Track status for levosimendan for the reduction of morbidity and mortality in cardiac surgery patients at risk for developing Low Cardiac Output Syndrome (LCOS). The company plans to start a Phase 3 trial with levosimendan in that indication during the third quarter of 2014, and has also developed a proprietary perfluorocarbon (PFC) therapeutic oxygen carrier called Oxycyte® that is currently in clinical and preclinical studies for intravenous delivery for indications such as traumatic brain injury, decompression sickness and stroke.

Caution Regarding Forward-Looking Statements

This news release contains certain forward-looking statements by the company that involve risks and uncertainties and reflect the company's judgment as of the date of this release. The forward-looking statements are subject to a number of risks and uncertainties, including, but not limited to matters beyond the company's control that could lead to delays in the clinical studies, delays in new product introductions and customer acceptance of these new products, and other risks and uncertainties as described in the company's filings with the Securities and Exchange Commission, including in its quarterly report on Form 10-Q filed on March 17, 2014, and annual report on Form 10-K filed on July 29, 2014, as well as its other filings with the SEC. The company disclaims any intent or obligation to update these forward-looking statements beyond the date of this release. Statements in this press release regarding management's future expectations, beliefs, goals, plans or prospects constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995.