



## **Leading BioSciences Announces Potential for Investigational Drug LB1148 to Treat Multiple Organ Dysfunction Syndrome in COVID-19 Patients**

*Company Publishes White Paper Outlining Potential Use of LB1148 to Alleviate Strain on the Healthcare System*

**CARLSBAD, CA – April 7, 2020** – Leading BioSciences, a drug development company focused on improving human health through therapeutic protection of the intestinal mucosal barrier, today announced it has developed a potential approach to treat COVID-19 patients suffering from acute respiratory distress syndrome (ARDS) and multiple organ dysfunction syndrome (MODS) using its investigational drug LB1148.

COVID-19 poses a serious global threat to patients and the healthcare system as a whole. Studies in the *New England Journal of Medicine* report 70% of critically ill COVID-19 patients experienced a shock/hypotension episode. A case fatality rate of 49% or higher is reported for COVID-19 patients who develop respiratory failure, septic shock, or MODS. Most forms of shock, including septic shock, feature disruption of the gastrointestinal (GI) mucosal barrier, leading to the escape of powerful digestive enzymes that accelerate the dangerous cascade of inflammation, cytokine storm, autodigestion and organ failure. Leading BioSciences' investigational drug, LB1148, is a novel formulation of the well-characterized protease inhibitor tranexamic acid being considered to treat ARDS/MODS in critically ill cases of patients infected with COVID-19.

Currently under development to treat organ dysfunction and reverse lethal complications of organ dysfunction associated with septic shock and major surgery, LB1148 is a novel oral liquid formulation designed to inhibit digestive enzyme activity and preserve gut integrity during intestinal distress (e.g., shock, infections, and surgeries). In clinical studies, LB1148 has demonstrated safety and improved GI function following major surgery. The active ingredient also has a good safety profile with more than 40,000 patients treated in clinical trials.

The company believes its mechanism of action may limit the viral load in patients with COVID-19 as the SARS-CoV-2 virus uses the ACE2 receptor, which is highly expressed in the lung and GI tract to infect epithelial cells of these organs. Recent work has shown that protease inhibitors may block the enzymatic activity required for COVID-19 infection through the ACE2 receptor. As a result, it is believed that LB1148 may reduce viral shedding and slow progression. The company has published a White Paper, which is available at <https://leadingbiosciences.com/lb1148-for-the-treatment-of-covid-19/> explaining the Company's rationale why it believes that LB1148 may be of potential use in treating COVID-19-associated organ failure.

“There is currently no proven treatment for COVID-19. The current standard of care for critically ill patients with COVID-19 is to place them on a ventilator with palliative care.

Unfortunately, today this means that three out of four of these patients will die. With limited resources such as ventilators, the key to a successful therapeutic for COVID-19 is to reduce the number of days patients are in the hospital and the time that patients are on ventilators. We believe there is a compelling rationale to test LB1148 in COVID-19 patients to improve these metrics,” said Tom Hallam, Ph.D., CEO of Leading BioSciences. “We implore the scientists, government officials, regulators and healthcare providers on front lines of this intensifying global pandemic to review our White Paper and take action to help us test LB1148 in clinical studies. Additionally, Leading BioSciences is accepting requests from physicians for access to LB1148. We will provide LB1148 at no cost for emergency individual compassionate use, with FDA permission, to ease the burden of COVID-19.”

### **About LB1148**

LB1148 is a patent-protected formulation of a broad-spectrum serine protease inhibitor designed to neutralize the activity of potent digestive proteases that can cause a range of serious complications and organ dysfunction if they escape the GI tract through a compromised mucosal barrier. By inhibiting the activity of digestive proteases, LB1148 has the potential to prevent damage to GI tissues, speed the return of GI function and shorten patients’ post-surgery stay in the ICU and hospital. This could substantially reduce the burden on the healthcare system, based upon the average cost of both ICU and hospital stays following cardiovascular surgery.

### **About Leading BioSciences**

Leading BioSciences is developing novel therapeutics designed to improve human health through therapeutic protection of the Gastrobiome™. The Company’s initial focus is combatting the interruption of GI function (ileus) following major surgery to reduce recovery times and shorten patients’ length of stay in the hospital. Additionally, the company believes that its investigational therapies have the potential to prevent the formation of post-operative adhesions (reducing hospital re-admissions and additional surgeries), as well as to address the myriad of health conditions and complications associated with chronic disruption of the intestinal mucosal barrier.

Learn more at: [www.leadingbiosciences.com](http://www.leadingbiosciences.com)

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