NEWS RELEASE

Leading BioSciences Teams with Donnelley Financial Solutions to Create Innovative Study Tool for Clinical Trial Monitoring During COVID-19 Pandemic

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Novel application will enable Leading BioSciences to remotely monitor phase 2 study data in patients with COVID-19 pneumonia

SAN FRANCISCO--(BUSINESS WIRE)--

Donnelley Financial Solutions (NYSE: DFIN), a leading risk and compliance company, today announced that Leading BioSciences, Inc. (LBS), a drug development company focused on improving human health through therapeutic protection of the intestinal mucosal barrier, is working with DFIN to manage remote monitoring of their COVID-19 study.

LBS is taking a unique approach to investigating treatments for COVID-19 by targeting gut integrity as a potential method of disrupting viral infection and potentially reducing life-threatening complications. The U.S. Food and Drug Administration (FDA) recently cleared LBS to conduct a phase 2 study of its lead investigational drug, LB1148, for the “treatment of pulmonary dysfunction associated with COVID-19 pneumonia.”

To carry out this study, LBS faces the challenge of collecting and monitoring patient data during a global pandemic with widespread implementation of shelter-in-place orders and hospital policy revisions prohibiting non-essential visitors.

Just as COVID-19 began to impact onsite clinical study monitoring operations across the globe, LBS began working with DFIN to utilize **Venue®** virtual data rooms as an innovative solution to virtually monitor patient data. Use of virtual data rooms allows LBS to continue trial operations and oversight in the absence of in-person visits to hospitals and clinical sites. LBS’s use of **Venue®** has proven to be a fast-track solution that reduces costs and has changed the way the company manages clinical trial execution. By allowing remote monitoring and source

document verification of clinical study data, LBS has been able to continue its development activities without compromising the safety of patient volunteers, or that of company and CRO team members.

“DFIN has revolutionized our management of the clinical trial monitoring process with their Venue data rooms,” said Inge K. Bear, Chief Development Officer at Leading BioSciences. “We have been able to reduce study costs, increase efficiency, maintain a safe work environment, and abide by all local, state and federal guidelines in the process. We will be incorporating Venue as part of our ‘new normal’ for managing clinical trial monitoring. Despite the operational disruptions of COVID-19, LBS will emerge as a more efficient organization because of our work with DFIN.”

“We are honored to be working with a company like Leading BioSciences who is on the forefront of combating the life-threatening complications related to COVID-19,” said Craig Clay, president of Global Capital Markets at DFIN. “While using our Venue solution, LBS has been able to securely and efficiently manage their investigational drug studies, while also reducing costs.”

About Donnelley Financial Solutions (DFIN)

DFIN is a leading global risk and compliance solutions company. We provide domain expertise, enterprise software and data analytics for every stage of our clients’ business and investment lifecycles. Markets fluctuate, regulations evolve, technology advances, and through it all, DFIN delivers confidence with the right solutions in moments that matter. Learn about DFIN’s end-to-end risk and compliance solutions online at **DFINsolutions.com** or you can also follow us on Twitter **@DFINSolutions** or on **LinkedIn**.

Forward-Looking Statements

This news release may contain "forward-looking statements" within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and the U.S. Private Securities Litigation Reform Act of 1995. Readers are cautioned not to place undue reliance on these forward-looking statements and any such forward-looking statements are qualified in their entirety by reference to the following cautionary statements. All forward-looking statements speak only as of the date of this news release and are based on current expectations and involve a number of assumptions, risks and uncertainties that could cause the actual results to differ materially from such forward-looking statements. Readers are strongly encouraged to read the full cautionary statements contained in Donnelley Financial Solutions’ (DFIN) filings with the SEC. Donnelley Financial Solutions (DFIN) disclaims any obligation to update or revise any forward-looking statements.

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 health conditions and complications associated with chronic disruption of the intestinal mucosal barrier. Learn more at: **www.leadingbiosciences.com**.

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 on the average cost of both ICU and hospital stays following cardiovascular surgery. LB1148 has not been approved for use in any indication, nor has it been deemed by FDA as "safe" for use in any patient population.

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