Bacthera and Seres Therapeutics Collaborate for Commercial Manufacturing of SER-109, a Potential Treatment Against Recurrent C. difficile Infection

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BASEL, Switzerland & CAMBRIDGE, Mass. & HORSHOLM, Denmark--(BUSINESS WIRE)--Nov. 10, 2021-- Bacthera, a specialized contract development and manufacturing organization (CDMO), and Seres Therapeutics, a leading microbiome therapeutics company, announced today a collaboration to manufacture SER-109, Seres' lead product candidate for recurrent *Clostridioides difficile* infection (rCDI). Under the terms of the agreement, Bacthera is establishing a dedicated facility for commercial manufacturing in its new Microbiome Center of Excellence, a manufacturing site dedicated to the production of LBPs located on Lonza's Ibex ® campus in Visp, Switzerland.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20211109006554/en/

SER-109 has the potential to be the first-ever live biotherapeutic product (LBP) to be produced commercially; the collaboration with Seres Therapeutics is a critical milestone for Bacthera, a joint venture between a Lonza Group Affiliate and Chr. Hansen. (Photo: Business Wire)

CDI, causing severe diarrhea and colitis, an inflammation of the colon, has been classified as one of the greatest microbial threats to human health by the Centers for Disease Control and Prevention (CDC). It is the leading cause of hospital-acquired infections in the United States and is responsible for 170,000 hospitalizations and the deaths of more than 20,000 Americans each year.[1] SER-109 is a potentially first-in-class investigational microbiome-based therapeutic consisting of bacterial spores from healthy human donors. This consortium of human microbiota from the gastrointestinal tract is designed to prevent further recurrences of *C. difficile* infections.

Lukas Schüpbach, CEO, Bacthera, commented: "Bacthera's ambition is to enable our customers such as Seres Therapeutics to bring life-changing treatments to patients by pioneering the Live Biotherapeutic Product industry. With this significant agreement, we are one step closer to making that happen, and we are proud to be part of bringing an entirely new class of medicines to people who have a profound need for it. With our new Microbiome Center of Excellence in Visp, we are looking forward to supporting the manufacturing of potentially life-saving microbiome-based treatments, such as SER-109."

Eric Shaff, CEO, Seres, added: "Our mission at Seres is to transform the lives of patients worldwide with revolutionary microbiome therapeutics. We are pleased with the progress we have made to prepare for an expected biologics license application submission in mid-2022, and look forward to partnering with Bacthera to expand upon our existing production capacity to meet demand growth beyond the initial phase of launch and help ensure eligible patients worldwide can receive this potential new treatment option."

Commercial manufacturing capacities

The agreement between Bacthera and Seres Therapeutics aims to expand upon Seres' initial commercial manufacturing supply chain. In addition to Seres' existing manufacturing infrastructure, the collaboration with Bacthera will expand the commercial production capacities of SER-109 and provide

supply support. SER-109 has the potential to be the first product within the entire live biotherapeutic industry to be produced commercially. To support the commercial manufacturing needs of SER-109 and other LBPs, Bacthera is establishing a new Microbiome Center of Excellence dedicated to LBP Manufacturing at Lonza's site in Visp, Switzerland.

The new Microbiome Center of Excellence will be based on Lonza's proven Ibex® Solutions concept for manufacturing, providing capacity for early commercial launches and production. The new Microbiome Center of Excellence will occupy an overall footprint of approximately 12'000 m^2 with three manufacturing floors, including capacity for commercial production. One of the three manufacturing floors will be dedicated to the manufacturing of SER-109.

Jean-Christophe Hyvert, President, Biologics and Cell and Gene, Lonza, commented: "This collaboration truly exemplifies Bacthera's leading offering for LBP manufacturing as a strategic partner on the path to commercialization. Bacthera will utilize a facility inspired by the Ibex® Solutions to offer flexibility, speed, and assured supply, enabling its customers to mark a significant milestone in the advance of microbiome-targeting therapies."

Under the terms of the agreement, Bacthera will provide GMP drug substance manufacturing and filling of the final drug product formulation into capsules. The capsules will leverage Lonza's Capsugel ® hypromellose (HPMC) plant-based capsule portfolio combined with encapsulation technologies that are scientifically designed to improve the stability of the product by ensuring protection from humidity, gastric acid, and other environmental factors.

Christian Barker, Executive Vice President Health & Nutrition, Chr. Hansen: "With Bacthera, we are on a mission to pioneer the future of medicine based on good bacteria. While Bacthera has already been successful in winning and executing several projects for customers based in Europe, the US, and Asia, we consider this first commercial manufacturing agreement a breakthrough in our microbiome lighthouse. This will support Bacthera in becoming a world-leading CDMO in the emerging Live Biotherapeutic Product industry."

About SER-109

SER-109 is an oral microbiome therapeutic candidate consisting of a consortium of highly purified Firmicutes spores, which normally live in the healthy microbiome. SER-109 is designed to prevent further recurrences of CDI in patients with a history of multiple infections by modulating the disrupted microbiome to a state that resists *C. difficile* colonization and growth. The SER-109 manufacturing purification process is designed to remove unwanted microbes, thereby reducing the risk of pathogen transmission beyond donor screening alone. The US FDA has granted SER-109 Breakthrough Therapy designation and Orphan Drug designation for the treatment of rCDI.

About Live Biotherapeutic Products

LBPs for short or more popularly known as bugs-as-drugs, are a new therapeutic modality being developed by a range of biotech and pharma companies across the world. LBPs are unique because their active substance is a living organism, most commonly a bacterium, that has been identified as showing promise in treating one or sometimes several diseases. LBPs are diverse and can consist of e.g., a single organism, a genetically modified organism, or a consortium of organisms.

About Bacthera

Bacthera was founded in 2019 as a 50:50 Joint Venture of Chr. Hansen A/S and a Lonza Group Affiliate to specifically serve the needs of the emerging LBP industry. Bacthera's expertise and the capabilities of production of bacteria for pharmaceutical purposes were transferred by both parent companies to Bacthera right from the beginning. Bacthera offers a compelling set of services across the LBP life cycle and process chain, from technical R&D development right through to GMP manufacture and QC testing of drug substance and drug product.

Bacthera operates from its Headquarters and Center of Excellence for drug product process development and manufacturing, and QC analytical testing in Basel, CH, and its Center of Excellence for drug substance process development, analytical development, and manufacturing in Hørsholm, DK.

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About Seres Therapeutics

Seres Therapeutics, Inc. (Nasdaq: MCRB) is a leading microbiome therapeutics company developing a novel class of multifunctional bacterial consortia that are designed to functionally interact with host cells and tissues to treat disease. Seres' SER-109 program achieved the first-ever positive pivotal clinical results for a targeted microbiome drug candidate and has obtained Breakthrough Therapy and Orphan Drug designations from the FDA. The SER-109 program is being advanced for the treatment of recurrent *C. difficile* infection and has potential to become a first-in-class FDA-approved microbiome therapeutic. Seres is evaluating SER-301 in a Phase 1b study in patients with ulcerative colitis and SER-155 in a Phase 1b study to address gastrointestinal infections, bacteremia, and graft-versus-host disease.

For more information, please visit **www.serestherapeutics.com**.

Seres entered into an **agreement** with Nestlé Health Science in July 2021 to jointly commercialize SER-109 in the US and Canada. Under the terms of the agreement, Nestlé Health Science will utilize its global pharmaceutical business, Aimmune Therapeutics, which has a strong presence in the field of gastroenterology, allowing it to lead the commercialization of SER-109 while providing Seres the ability to retain a strategic role and actively participate in the launch.

About Lonza

Lonza is the preferred global partner to the pharmaceutical, biotech, and nutrition markets. We work to enable a healthier world by supporting our customers to deliver new and innovative medicines that help treat a wide range of diseases. We achieve this by combining technological insight with world-class manufacturing, scientific expertise, and process excellence. Our unparalleled breadth of offerings enables our customers to commercialize their discoveries and innovations in the healthcare sector.

Founded in 1897 in the Swiss Alps, today, Lonza operates across five continents. With approximately 15,000 full-time employees, we comprise high-performing teams and individual talent that make a meaningful difference to our own business, as well as to the communities in which we operate.

The company generated sales of CHF 2.5 billion with a CORE EBITDA of CHF 847 million in H1 2021. Find out more at **www.lonza.com**

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About Chr. Hansen

Chr. Hansen is a global, differentiated bioscience company that develops natural ingredient solutions for the food, nutritional, pharmaceutical, and agricultural industries. At Chr. Hansen we are uniquely positioned to drive positive change through microbial solutions. We have worked for over 145 years to enable sustainable agriculture, better food, and healthier living for more people around the world. Our microbial and fermentation technology platforms, including our broad and relevant collection of around 40,000 microbial strains, have game-changing potential. Matching customer needs and global trends, we continue to unlock the power of good bacteria to respond to global challenges such as food waste, global health, and the overuse of antibiotics and pesticides. As the world's most sustainable food ingredients company, we touch the lives of more than 1 billion people every day. Driven by our legacy of innovation and curiosity to pioneer science, our purpose – To grow a better world. Naturally. – is at the heart of everything we do.

Additional Information and Disclaimer

Lonza Group Ltd has its headquarters in Basel, Switzerland, and is listed on the SIX Swiss Exchange. It has a secondary listing on the Singapore Exchange Securities Trading Limited ("SGX-ST"). Lonza Group Ltd is not subject to the SGX-ST's continuing listing requirements but remains subject to Rules 217 and 751 of the SGX-ST Listing Manual.

Certain matters discussed in this news release may constitute forward-looking statements. These statements are based on current expectations and estimates of Lonza Group Ltd, although Lonza Group Ltd can give no assurance that these expectations and estimates will be achieved. Investors are cautioned that all forward-looking statements involve risks and uncertainty and are qualified in their entirety. The actual results may differ materially in the future from the forward-looking statements included in this news release due to various factors. Furthermore, except as otherwise required by law, Lonza Group Ltd disclaims any intention or obligation to update the statements contained in this news release.

Chr. Hansen's forward-looking statements

This press release contains forward-looking statements that reflect management's current views with respect to certain future events and potential financial performance. Forward-looking statements are other than statements of historical facts. The words "believe," "expect," "anticipate," "intend," "estimate," "outlook," "will," "may," "continue," "should" and similar expressions identify forward-looking statements. Forward-looking statements include statements regarding: objectives, goals, strategies, outlook and growth prospects; future plans, events or performance and potential for future growth; liquidity, capital resources and capital expenditures; economic outlook and industry trends; developments of the Company's markets; the impact of regulatory initiatives; and the strength of competitors. The forward-looking statements in this press release are based upon various assumptions, many of which are based, in turn, upon further assumptions, including without limitation, management's examination of historical operating trends, data contained in records and other data available from third parties. Although the Company believes that these assumptions were reasonable when made, these assumptions are inherently subject to significant known and unknown risks, uncertainties, contingencies and other important factors which are difficult or impossible to predict and may be beyond our control. Such risks, uncertainties, contingencies and other important factors could cause the actual results of the Company or the industry to differ materially from those results expressed or implied in this press release by such forward-looking statements. The information, opinions and forward-looking statements contained in this report speak only as at the date of this press release, and are subject to change without notice. The Company and its respective agents, employees or advisors do not intend to, and expressly disclaim any duty, undertaking or obligation to, make or disseminate any supplement, amendment, update or revision to any of the information, opinions or forward-looking statements contained in this press release to reflect any change in events, conditions or circumstances beyond what is required by applicable law or applicable stock exchange rules and regulations.

Seres Therapeutics Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including Seres' manufacturing plans and the potential benefits of Seres' collaboration with Bacthera, the potential approval of SER-109 and its status as a first-in-class therapeutic and as the first-ever live biotherapeutic product, the timing of a BLA filing and of initiating commercial manufacturing, the potential of microbiome therapeutics to treat and prevent disease, the timing and results of Seres' clinical studies, the ultimate safety and efficacy data for Seres' products, and other statements which are not historical fact.

These forward-looking statements relating to Seres are based on Seres' management's current expectations. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, the following: Seres has incurred significant losses, is not currently profitable and may never become profitable; Seres' need for additional funding; Seres' limited operating history; the impact of the COVID-19 pandemic; Seres' unproven approach to therapeutic intervention; and Seres' reliance on third parties and collaborators to manufacture product candidates and develop and commercialize product candidates, if approved. These and other important factors discussed under the caption "Risk Factors" in Seres' Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission, or SEC, on August 3, 2021, and its other reports filed with the SEC could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. Any such forward-looking statements about Seres represent Seres' management's estimates as of the date of this press release. While Seres may elect to update such forward-looking statements at some point in the future, it disclaims any obligation to do so, even if subsequent events cause Seres' views to change. These forward-looking statements should not be relied upon as representing Seres' views as of any date subsequent to the date of this press release.

[1] ***Clinical Infectious Diseases, 72, 12, 2132–2140.***

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