Lonza and Selecta Biosciences Announce Manufacturing Agreement for Anc80-AAV-Based Gene Therapy for Treatment of Methylmalonic Acidemia

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BASEL, Switzerland and WATERTOWN, Mass., Feb. 16, 2017 (GLOBE NEWSWIRE) -- Lonza Houston, Inc., a global leader in viral gene and cell therapy manufacturing, and Selecta Biosciences, Inc. (NASDAQ:SELB), a clinical-stage biopharmaceutical company focused on developing biologic therapies for rare and serious diseases that avoid unwanted immunogenicity, have entered into a strategic manufacturing agreement. Under the terms of the agreement, Lonza will produce an Anc80-AAV-based gene therapy product for Selecta's proprietary program for the treatment of Methylmalonic Acidemia (MMA), a rare inborn error of metabolism, and may in the future produce other Anc80-based products for which Selecta holds exclusive options.

This relationship will leverage Lonza's expertise in the development of robust and industry-scale manufacturing platforms for viral-based products. Data shows that Anc80-AAV, an in silico-designed synthetic gene therapy vector, has the potential to provide superior gene expression levels in retina, liver, muscle, cochlea's outer hair cells and other tissue targets in preclinical studies, as well as reduced cross-reactivity as compared to naturally occurring adeno-associated viral vectors (AAVs) that are currently in clinical development.

"This agreement with Selecta Biosciences continues to demonstrate Lonza's leadership position in the cell and gene therapy space," said Andreas Weiler, Ph.D., Head of Emerging Technologies Business Unit for Lonza's Pharma&Biotech segment. "Lonza will utilize our extensive cGMP manufacturing knowledge and world-class quality systems to help Selecta Biosciences develop promising novel therapeutics for patients impacted by MMA and other devastating diseases."

"We at Selecta are focused on combining novel and proprietary viral vectors with our immune tolerance Synthetic Vaccine Particles (SVP™) to enable the first non-immunogenic gene therapies, providing the potential for repeat dosing," said Werner Cautreels, Ph.D., Selecta's president, CEO and chairman. "We view Lonza – one of the industry's largest contract manufacturers of biologics and a leading supplier in gene therapy – as an ideal partner. They already have invested in developing various expression technologies, and they share our excitement about Anc80. We look forward to working with them to bring the first Anc80-based program into the clinic as a potential treatment for patients afflicted with MMA."

About Selecta's MMA Program

MMA is an inborn error of metabolism that, according to the National Institutes of Health (NIH), affects an estimated one in 25,000 to 48,000 individuals globally. MMA patients are unable to process certain proteins and fats, leading to the accumulation of toxic metabolites. Symptoms start to develop in early childhood and, despite strict diet, patients suffer from a wide range of disease-related complications such as pancreatitis, strokes and chronic kidney failure. Selecta exclusively licensed Anc80 for MMA from Massachusetts Eye and Ear® (MEE) in May 2016. Under the license agreement, Selecta also has the exclusive option to develop gene therapies using Anc80 for additional pre-defined lysosomal storage, genetic muscular and genetic metabolic diseases.

Selecta intends to combine Anc80 with recently discovered transgenes and Selecta's SVP-Rapamycin to create a novel gene therapy candidate for MMA. This candidate is intended to a) enable the treatment of patients with and without pre-existing anti-AAV antibodies; b) prevent cellular immune responses that often reduce the expression levels of gene therapies; and c) provide the ability to administer repeat gene therapy doses to achieve sufficient levels of methylmalonyl-CoA mutase (MUT), the enzyme that MMA patients are lacking.

To advance the MMA program, Selecta entered into a Collaborative Research and Development Agreement (CRADA) with MEE and the National Human Genome Research Institute, NIH, in 2016. Principal investigators in this CRADA initiative are Charles Venditti, MD, PhD, Senior Investigator and Head, Organic Acid Research Section, Medical Genomics and Metabolic Genetics Branch and Luk Vandenberghe, PhD, Director of the Grousbeck Gene Therapy Center at MEE and an Assistant Professor at Harvard Medical School. A physician-scientist specializing in the study of inborn errors of metabolism including MMA, Dr. Venditti and his group have published several studies showing the effectiveness of gene therapy as a treatment for MMA in mice. Dr. Vandenberghe from MEE is the inventor of Anc80.

About Lonza

Lonza is one of the world's leading and most-trusted suppliers to the pharmaceutical, biotech and specialty ingredients markets. It harnesses science and technology to create products that support safer and healthier living and that enhance the overall quality of life.

Not only is Lonza a custom manufacturer and developer, the company also offers services and products ranging from active pharmaceutical ingredients to drinking water sanitizers, from nutritional and personal care ingredients to agricultural products, and from industrial preservatives to microbial control solutions that combat dangerous viruses, bacteria and other pathogens.

Founded in 1897 in the Swiss Alps, Lonza today is a well-respected global company with approximately 40 major manufacturing and R&D facilities and more than 10,000 full-time employees worldwide. The company generated sales of CHF 4.13 billion in 2016 and is organized into two market-focused segments: Pharma&Biotech and Specialty Ingredients. Further information can be found at www.lonza.com.

About Selecta Biosciences, Inc.

Selecta Biosciences, Inc. is a clinical-stage biopharmaceutical company focused on developing biologic therapies for rare and serious diseases that avoid the immune responses that compromise efficacy and lead to life-threatening complications. Selecta is applying its proprietary Synthetic Vaccine Particles (SVP™) to a range of therapeutic areas in which immunogenicity is a key challenge. SEL-212, the company's lead candidate in Phase 2, is being developed to treat chronic refractory gout patients and reduce their debilitating symptoms, including flares and inflammatory arthritis. Further, Selecta's two proprietary gene therapy product candidates have the unique potential to enable repeat administration, allowing for dose adjustment in patients and maintenance of therapeutic activity over time. The company is seeking to expand the use of its SVP platform in other areas, such as immuno-oncology, allergies, autoimmune diseases and vaccines. Selecta is based in Watertown, Massachusetts. For more information, please visit http://selectabio.com.

Additional Lonza 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 presentation 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 release.

Selecta Biosciences, Inc. Disclaimer

Any statements in this press release about the future expectations, plans and prospects of Selecta Biosciences, Inc. ("the company"), including without limitation, statements regarding the development of its pipeline, the ability of the company's SVP platform, including SVP-Rapamycin, to mitigate immune response and create better therapeutic outcomes, the potential treatment applications for products utilizing the SVP platform in areas such as gene therapy, immuno-oncology, allergies, autoimmune diseases and vaccines, whether the company's proprietary gene therapy product candidates will enable repeat administration, allow for dose adjustment in patients or maintain therapeutic activity over time, the sufficiency of the company's cash, cash equivalents, investments, and restricted cash and other statements containing the words "anticipate," "believe," "continue," "could," "estimate," "expect," "hypothesize," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "would," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including, but not limited to, the following: the uncertainties inherent in the initiation, completion and cost of clinical trials including their uncertain outcomes, the unproven approach of the company's SVP technology, undesirable side effects of the company's product candidates, its reliance on third parties to manufacture its product candidates and to conduct its clinical trials, the company's inability to maintain its existing or future collaborations, licenses or contractual relationships, its inability to protect its proprietary technology and intellectual property, potential delays in regulatory approvals, the availability of funding sufficient for its foreseeable and unforeseeable operating expenses and capital expenditure requirements, substantial fluctuation in the price of its common stock, a significant portion of the company's total outstanding shares have recently become eligible to be sold into the market, and other important factors discussed in the "Risk Factors" section of the company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission, or SEC, on November 10, 2016, and in other filings that the company makes with the SEC. In addition, any forward-looking statements included in this press release represent the company's views only as of the date of its publication and should not be relied upon as representing its views as of any subsequent date. The company specifically disclaims any obligation to update any forward-looking statements included in this press release.

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