Goodwin Biotechnology Announces the Completion of cGMP Manufacturing of an IgM Monoclonal Antibody and IgM : Ligand Conjugate for Q Therapeutics, and Successful Clearance of Q Therapeutics’ IND Submission for Q-Cells® Cell Therapy in ALS

July, 2015 -- Plantation, Florida -- Goodwin Biotechnology, Inc., a biological Contract Development and Manufacturing Organization (CDMO) that specializes in bioprocess development and GMP manufacturing of biopharmaceuticals utilizing Mammalian Cell Culture expression systems and Bioconjugation technologies, has partnered with Q Therapeutics, Inc., a clinical-stage developer of novel cellular therapies for central nervous system (CNS) diseases to provide GMP antibodies for manufacture of clinical trial materials. To do so, Goodwin Biotechnology completed Process Development, Scale Up, and cGMP manufacturing of an IgM antibody and an IgM: Ligand Conjugate used in the isolation of Q-Cells®, the first patented cellular therapeutic product candidate from Q Therapeutics under development for the treatment of Amyotrophic Lateral Sclerosis (ALS), also known as Lou Gehrig’s disease.

“Q-Cells are glial-restricted progenitor cells (GRPs) – early descendants of neural stem cells that produce only ‘glia’ – which make up 50 percent of cells in the brain, and are essential for supporting, maintaining and even restoring neuron health. Based on the recently cleared Investigational New Drug Application (IND) from the U.S. Food and Drug Administration (FDA), we’re now on the cusp of performing groundbreaking human studies for the treatment of patients with ALS,” said Deborah Eppstein, PhD, President & Chief Executive Officer at Q Therapeutics. “This important milestone is a testament to the commitment and dedication of all of our scientific co-workers and supporters, that include the National Institute of Neurological Disorders and Stroke Translational Research Program (U01-NS06713) at the National Institutes of Health, the Maryland Stem Cell Research Fund, Bosarge Life Sciences, Nicholas Maragakis, MD, at Johns Hopkins University, MPI Research, Inc., the Biologics Consulting Group, and the Cell Therapy and Regenerative Medicine Facility (CTRM) at the University of Utah.”

“We are very pleased with the highly skilled scientists at Goodwin Biotechnology, who met the challenge of developing and scaling up the process to manufacture a monoclonal antibody using their perfusion cell culture process, and utilizing their bioconjugation expertise to prepare the IgM-ligand conjugate needed for purification of our Q-Cells®, while overcoming the many process and product-related challenges associated with an IgM antibody,” added James Campanelli, PhD, Vice President of Research and Development at Q Therapeutics. “We also were very pleased with their preparation of the portions of the CMC section concerning this antibody for our IND submission, which has recently received clearance by the FDA, to proceed with Phase 1/2a clinical trials to evaluate the use of Q-Cells® in treating ALS patients. This is a significant milestone for these patients and their families, as well as for both companies.”

“This is an excellent example that utilized the breadth of our capabilities at Goodwin Biotechnology,” noted Muctarr Sesay, PhD, Chief Scientific Officer at Goodwin Biotechnology. “The technical team at Goodwin prides themselves in all facets of this project and being able to minimize the potential aggregation, stability, formulation, bioconjugation, and purification issues associated with a hybridoma IgM monoclonal antibody reflects our solutions oriented approach that we apply to all projects. We are proud to have partnered with and provided consultation to Q Therapeutics over the last 6 years where we manufactured the IgM and conjugated the antibody with a ligand and leveraged the regulatory skill sets of our team to prepare the antibody portion of the CMC section for their IND submission.”

ALS is a devastating condition caused by degeneration of motor neurons, the nerve cells in the brain and spinal cord that control muscle movement. ALS affects more than 30,000 people in the U.S. at any given time and nearly half a million people worldwide. To date, there has been no effective therapy for ALS and it is 80% fatal within five years of diagnosis.

Q Therapeutics selected ALS as the first clinical indication for Q-Cells based on a combination of the large unmet medical need and the significant scientific rationale supporting the multiple pathways by which healthy glial cells are believed to protect and preserve the function of motor neurons.
About Goodwin Biotechnology, Inc.

Goodwin Biotechnology is a uniquely qualified CDMO that offers a Single Source Solution™ for our clients from cell line development, exploratory proof of concept projects through process development and cGMP contract manufacturing of monoclonal antibodies, recombinant proteins, vaccines, and Biologic Drug Conjugates including Antibody Drug Conjugates (ADCs) for early and late stage clinical trials. By working with Goodwin Biotechnology, clients can enhance the value of their product candidates with clear development and manufacturing strategies, as well as a road map to meet the appropriate quality requirements from the milligram and gram range to kilogram quantities as the product candidates move along the clinical development pathway in a cost-effective, timely, and cGMP compliant manner to enhance patients’ lives. With 23 years of experience as an independent integrated contract manufacturer, Goodwin Biotechnology has worked as a strategic partner with companies of all sizes from small university spin-offs to major research institutes, government agencies and large, established and multi-national biopharmaceutical companies. Based on the impressive track record, Goodwin Biotechnology was recently awarded Frost & Sullivan’s Customer Value and Leadership Award for Best Practices in Mammalian Contract Manufacturing! Additional information may be found at http://www.GoodwinBio.com.

About Q Therapeutics, Inc.

Headquartered in Salt Lake City, Q Therapeutics is a fully reporting, non-trading clinical stage company developing adult stem cell therapies to treat debilitating diseases and injuries of the central nervous system. The Company’s first product candidate, Q-Cells®, is a cell-based therapeutic intended to restore or preserve normal activity of neurons by providing essential support functions that occur in healthy central nervous system tissues. Q-Cells may be applicable to a wide range of central nervous system diseases, including demyelinating conditions such as multiple sclerosis, transverse myelitis, cerebral palsy and stroke; as well as other neurodegenerative diseases and injuries, such as ALS (Lou Gehrig’s disease), Huntington’s disease, spinal cord injury, stroke, traumatic brain injury, Parkinson’s disease and Alzheimer’s disease. Q Therapeutics’ initial clinical target is ALS, with a first IND now cleared to proceed by the FDA. The Company’s proprietary product pipeline also encompasses neural cell products derived from induced pluripotent stem cells (iPSC). For more information, please visit www.qthera.com.

For more information, please contact:

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Cautionary Statement Regarding Forward Looking Information – This news release may contain forward-looking statements made pursuant to the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. Investors are cautioned that such forward-looking statements in this press release regarding potential applications of Q Therapeutics’ technologies constitute forward-looking statements that involve risks and uncertainties, including, without limitation, risks inherent in the development and commercialization of potential products, uncertainty of clinical trial results or regulatory approvals or clearances, need for future capital, dependence upon collaborators and maintenance of its intellectual property rights. Actual results may differ materially from the results anticipated in these forward looking statements. Additional information on potential factors that could affect results and other risks and uncertainties are detailed from time to time in Q Therapeutics’ periodic reports, including the quarterly report on Form 10-Q for the period ended March 31, 2015 and the Company’s Annual Report on Form 10-K for the year ended December 31, 2014.