Goodwin Biotechnology Expands its ADC Capabilities with a High Containment Suite for Development and cGMP Manufacturing of Cytotoxic ADCs

May 2016 -- Plantation, Florida -- Goodwin Biotechnology, Inc., a biological Contract Development and Manufacturing Organization (CDMO) that specializes in bioprocess development and cGMP manufacturing of biopharmaceuticals today announced that it has recently expanded its Bioconjugation capabilities by adding a dedicated suite for developing and manufacturing cytotoxic Antibody Drug Conjugates (ADCs) up to Safebridge level 4/5.

"For over 15 years, Goodwin Biotechnology has been one of the pioneers in providing development and GMP manufacturing of a broad portfolio of ADC projects, including cytotoxic ADCs, Radio-Immunoconjugates, Antibody-Peptide Conjugates, Antibody-Dye Conjugates, PEGylated proteins, other bioconjugates, and even Biobetters," said Muctarr Sesay, PhD, Chief Scientific Officer and VP, Bioconjugation Development at Goodwin Biotechnology. "Our experience in Bioconjugation has resulted in several patents and publications, as well as proprietary processes that enable us to help our clients overcome some significant challenges in developing their next generation of ADCs. Given the increasing interest in conjugating highly cytotoxic products (e.g., anti-cancer drugs) to enhance the efficacy of ADCs, we have added a dedicated ISO-7 Cytotoxic Process facility for Proof of Concept, development, Tox and cGMP manufacturing to address unmet clinical needs."

"We have built a very productive relationship with Goodwin Biotechnology over the past 18 months," said Jostein Dahle PhD, Chief Scientific Officer at Nordic Nanovector ASA, a Norway based, biopharmaceutical company. "They listen closely and are responsive to our needs. This collaborative approach is helping to develop a flexible manufacturing process for the successful GMP production of antibody radionuclide conjugates, or ARCs, for clinical trials with potential for future commercial scale up."

"I have found that working with the team at Goodwin Biotechnology has been a great pleasure," noted Miguel Garcia-Guzman, Ph.D., President and Chief Executive Officer at Aspyrian Therapeutics, a California based, clinical stage biotech company. "We were originally impressed by their expertise in Bioconjugation. This perception was reinforced by the flexible and solutions-oriented approach to the complexity of our project, a first-in-class, precision targeted therapy for cancer. They treated our product as theirs as they orchestrated a flexible and well-run process in successfully generating Tox and cGMP materials, which performed well in preclinical animal studies and on-going human clinical trials. As a result, we secured our firm's first IND submission, which was a crucial milestone for our company. It speaks about the quality, timeliness, and process economics that Goodwin Biotechnology puts into every aspect of their work."

"We collaborate with many of our clients in the early stages of proof of concept/development of the conjugation process by empirically recommending the appropriate linkers, payloads, and the bioconjugation chemistries and processes to create a viable ADC candidate. We then blend that with a solutions-oriented approach to help our clients overcome significant challenges, including aggregation, especially that associated with IgM antibodies and conjugates, multiparameter optimization, optimizing drug-to-antibody ratios (DAR), working with antibody fragments, purification challenges, drug solubility issues, process scalability and economics, etc.," Dr. Sesay continued. "We have developed proprietary processes to help address many of those challenges. We have also overcome the challenges associated with random conjugations with site-directed conjugation of radionuclide chelators and other payloads and ligands to antibodies which results in narrower DAR (drug-to-antibody mole ratios), improved conjugate binding and, hopefully, an enhanced therapeutic index."

"We are proud of the expertise that we have developed in area of Bioconjugation and the successful work that we have done with over 40 client projects over more than a decade," said Karl Pinto, Chief Executive Officer at Goodwin Biotechnology, Inc. "Goodwin continues to invest strategically in our Bioconjugation business in order to enhance the breadth and depth of what we can offer to our clients. These Bioconjugation capabilities complement our over 23 years of experience in manufacturing monoclonal antibodies, recombinant proteins, and vaccines through mammalian cell culture expression systems. So, as part of our Single Source Solution™, Goodwin is uniquely qualified to partner with our clients to develop customized and flexible approaches for manufacturing the 'naked' antibodies, then follow with the appropriate conjugation activities to cost effectively address their needs and deliver their ADC candidates on time."

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 over 20 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 has been awarded **Frost & Sullivan's Customer Value and Leadership Award for Best Practices in Mammalian Contract Manufacturing**! In addition, Goodwin Biotechnology was awarded '**Best in Sector: Biopharmaceutical Contract Development & Manufacturing**' at *Acquisition International* magazine's 2015 Sector Performance Awards. Most recently, Goodwin Biotechnology received *Global Health & Pharma's* 2016 award for **Best for BioProcess Development & cGMP Manufacturing**. Click here to view the press releases! Additional information may be found at http://www.GoodwinBio.com.

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