Goodwin Biotechnology announces the appointment of Gerald ("Jerry") Orehostky as Vice President, Quality and Regulatory

Fort Lauderdale, FL, August 5, 2019 /PRNewswire/ -- Goodwin Biotechnology, Inc. ("Goodwin") announced that it has recruited Gerald (Jerry) Orehostky to join the company as Vice President, Quality and Regulatory.

Goodwin Biotechnology uniquely meets the contract development and manufacturing needs for today's complex, targeted biopharmaceuticals. As a full GMP, FDA-registered and inspected biopharmaceuticals Contract Development and Manufacturing Organization (CDMO), Goodwin has continued its expansion to add commercial cGMP solutions to augment its offering of a fully integrated Single Source Solution™ from Cell Line Development, Process Development including Bioconjugation, Scale-Up, cGMP Contract Manufacturing and Aseptic Fill/Finish of mammalian cell-culture derived life-saving monoclonal antibodies, recombinant proteins, vaccines, and Antibody Drug Conjugates (ADCs).

"Jerry has more than 30 years of broad experience in Quality Systems, Regulatory Affairs, Regulatory Compliance, QA, Product Development and Commercial Operations in Biologics, Bioconjugation, and other therapeutic areas," said Karl Pinto, CEO of Goodwin Biotechnology. "His extensive experience and, in-depth functional proficiency in Quality Assurance & Regulatory Affairs from early stage to commercial products will help guide Goodwin as we continue our expansion plans to continue our nearly 30-year legacy of servicing our clients in bringing their products into, and through the clinic with our unmatched service, flexibility, and quality. We are now transcending the clinic and taking the company into commercial manufacturing, and Jerry's leadership will be instrumental towards this endeavor."

"I was intrigued by Goodwin's efficient size, experience, and breadth of capabilities," noted Jerry Orehostky, VP, Quality and Regulatory. "The company is well positioned to serve cutting edge 'new & complex biologics' that will greatly benefit from customized processes and simplified supply chains for biopharmaceutical candidates. Such clients and products are very well served by Goodwin, a company that focuses on small-to-mid volume development and manufacturing to seamlessly progress from the clinic and into the commercial market within today's shortened and abbreviated clinical pathways."

"Jerry has held leadership positions within Regulatory Affairs and Quality Operations at companies such as Actinium Pharmaceuticals, Antares Pharma, Discovery Laboratories, Palatin Technologies, Schering-Plough, Vivus, and Interferon Sciences," continued Mr. Pinto. "He maintained a high level of compliance through Product Development and Commercial Operations and was responsible for the generation and submission of applications and registrations for several products that were successful in attaining US, Canadian, and EU marketing authorizations. I look forward to working with him and other members of the Goodwin team to scale our business as our clients and the market demand, and ultimately help patients who are desperately in need of the newest medical technologies being developed."

About Goodwin Biotechnology, Inc.

Goodwin Biotechnology uniquely meets the contract development and manufacturing needs for today's complex, targeted biopharmaceuticals. With the infrastructure, experience, skills, cutting edge technologies, and flexibility, Goodwin overcomes and resolves Development and Manufacturing Challenges- all within one location and a single quality system. This Single Source Solution™ helps move Biopharmaceutical candidates 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 through to commercial production. 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 27 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. Last year, Goodwin Biotechnology received Global Health & Pharma's 2017 award for Best for BioProcess Development & cGMP Manufacturing and Best in Mammalian Cell Culture Process Development & cGMP Manufacturing. In 2018, Goodwin Biotechnology was named Biologics cGMP Manufacturer of the Year 2018 by Global Health & Pharma News. Click here to view the press releases! Additional information may be found at http://www.GoodwinBio.com.

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