



Goodwin Biotechnology Announces a Collaboration with Aspyrian Therapeutics for cGMP Manufacturing of an Innovative Antibody Drug Conjugate

March, 2014 -- Plantation, Florida -- Goodwin Biotechnology, Inc. announced an agreement with Aspyrian Therapeutics, Inc. for the technology transfer, process development, scale-up, and cGMP manufacturing of a novel Antibody Drug Conjugate (ADC) for use in Phase I clinical trials.

Aspyrian Therapeutics has secured an exclusive license from the National Cancer Institute for a new ADC technology platform, Near-infrared Photoimmunotherapy (PIT), which permits highly efficient and selective ablation of tumor cells while sparing damage to critical structures adjacent to the tumor. Because the payload in this unique ADC is inert until it is both in the tumor and activated by near-infrared (NIR) light, it overcomes the dose-limiting adverse effects that have hindered the development of conventional, toxin-loaded ADC systems.

“We are pleased to have been selected to partner with Aspyrian Therapeutics for this leading edge ADC project,” said SooYoung Lee, PhD, Chief Operating Officer at Goodwin Biotechnology. “This important project is a testament to our experience and expertise in bioconjugation that has been developed and refined over more than a decade. This initiative has been led by Muctarr Sesay, PhD, Vice President of Process Development who is one of the pioneers in process development and cGMP manufacturing of many ADCs and biologic drug conjugates, which Goodwin has successfully manufactured for human clinical studies.”

“The technical expertise that Goodwin Biotechnology offers in the field of bioconjugation, coupled with the responsiveness and flexibility they exhibited during the selection process, made them the obvious choice,” noted Miguel Garcia-Guzman, PhD, Chief Scientific Officer at Aspyrian Therapeutics. “Our mission is to leverage the potential of the PIT platform by developing a pipeline of proprietary and partnered ADC products, and this collaboration represents a critical milestone in this endeavor.”

Near-infrared Photoimmunotherapy (PIT) is based on three components:

1. An antibody that binds to cell-surface antigens.
2. The NIR IR700DX dye conjugated to the antibody via a stable linkage.
3. NIR light dosimetry to activate the conjugate (cell killing occurs whether the conjugate is surface-bound or internalized).

Upon administration of non-ionizing NIR light, PIT induces rapid cell killing by localized disruption of cell membranes of only those cells targeted by the antibody conjugate. Importantly, unbound conjugates and free dye do not elicit any phototoxicity upon NIR irradiation. The combination of selective binding to surface antigens and organ-localized NIR activation permits highly efficacious disease-specific ablation, while sparing nearby healthy tissues and structures.

About Goodwin Biotechnology, Inc.

Goodwin Biotechnology is a world-class CMO that offers a Single Source Solution™ through partnerships with clients for cell line development or exploratory proof of concept projects through process development and cGMP contract manufacturing of monoclonal antibodies, recombinant proteins, vaccines, and Antibody Drug Conjugates (ADCs) and other Biologic Drug Conjugates for early and late stage clinical trials. By working with Goodwin Biotechnology, our clients can enhance the value of their product candidates with clear development and manufacturing strategies as well as a road map to meet the highest quality product requirements from the milligram and gram range to kilogram quantities as the product candidates move along the clinical approval pathway in a cost-effective, timely, and cGMP compliant manner to enhance patients' lives. With over 20 years of experience as an independent 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. Additional information may be found at <http://www.GoodwinBio.com>.

About Aspyrian Therapeutics, Inc.

Aspyrian Therapeutics is a San Diego-based start-up biotechnology company. Together with its collaborators, Aspyrian aims to develop a novel class of ADCs that enable local control of tumors without damaging nearby healthy organs, tissues and structures. Aspyrian plans to advance its first product into the clinic by the end of 2014 for the treatment of head and neck cancers, with the intent to obtain Phase I data, including safety and anticancer responses, by the end of 2015. Additional information may be found at <http://www.aspyriantherapeutics.com/>.

For more information on the process development and GMP manufacturing of biologics, please contact Goodwin Biotechnology:

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