Radimmune Therapeutics Selected Goodwin Biotechnology for Process Development through cGMP Manufacturing of their IgG Monoclonal Antibody and Conjugate.

November, 2018 – Plantation, Florida – Radimmune Therapeutics has selected Goodwin Biotechnology, Inc. to develop a process and manufacture it's lead therapeutic oncology candidate for clinical development, a therapeutic grade IgG monoclonal antibody (mAb) conjugate. The conjugate will be radiolabeled with ^{213}Bi and administered to patients in a Phase I clinical study for the treatment of melanoma.

"Melanoma is by far the deadliest form of skin cancer," said Robert Wittig, Chief Operating Officer at Radimmune Therapeutics. "Globally, there are approximately 3.1 million individuals with active disease and nearly 60,000 deaths annually. The rising incidence of melanoma of 170,000 new cases diagnosed each year is expected to accelerate the demand for anticancer agents. RadImmune Therapeutics has developed a novel therapeutic approach leveraging its unique and proprietary monoclonal antibody (mAb) platform as a Radioimmunotherapeutic (RIT) agent. This cancer treatment modality utilizes monoclonal antibodies (mAbs) chemically linked to a radioactive atom (radionuclide), and targeted against a specific antigen in the melanoma cancer cell microenvironment. RadImmune's treatment is infused, and then binds to the target antigen resulting in systemic administration of focused therapeutic radiation to tumor cells, while sparing normal tissues from the toxic effects of radiation."

"One of the most exciting recent advances in Molecular Targeted Radiotherapy has been in the area of Alpha Emitting Radioimmunotherapy," noted Dr. David Rickles, Chief Scientific Officer at Radimmune Therapeutics. "Alpha emitting radionuclides can be linked to custom mAbs via a chelator, and then targeted to highly cancer specific antigens for a new, potentially more effective approach to RIT, a form of Molecular Targeted Radiotherapy. The relative biologic effectiveness (RBE) is the standard measure of cytotoxic potency for therapeutic radiation. Remarkably, alpha rays have an RBE 20 times that of any of the other types of radiation therapy (beta, gamma, X-ray photons, and proton beam). Another attractive feature of alpha rays is their extremely short path length in tissue of about 50 microns, or 5 cells diameter. An alpha emitting, cancer specific, targeted drug could therefore offer true micro precision, in terms of normal tissue sparing. By potentially combining very low toxicity with high potency; Alpha emitting RIT holds great promise for future development."

"We selected Goodwin Biotechnology for this important project based in part on experience working with them on similar projects over a number of years, coupled with impressive references from clients for whom they have recently performed high quality work," noted Robert Wittig. "Being a smaller company, we found them to be flexible in their approach and a very good fit for RadImmune. They transparently develop sound process development, manufacturing, and product characterization

strategies, and have a long history of overcoming challenges while maintaining a rapid development timeline."

"We're excited about the opportunity to partner with Radimmune Therapeutics to advance the treatment of melanoma," commented Karl Pinto, Chief Executive Officer at Goodwin Biotechnology. "Our highly skilled scientific staff takes great pride in delivering the highest quality product on time and within the agreed upon budget. Further, our commitment to provide commercial manufacturing capabilities is well underway and the timing for companies such as Radimmune Therapeutics is perfect to meet their need now and well into the future."

"We have a unique approach in being able to optimize the process, manufacture the mAb under cGMP conditions, and then conjugate the mAb to any one of a variety of chelators," indicated Muctarr Sesay, PhD, Chief Scientific Officer at Goodwin Biotechnology. "For this project, Goodwin will develop and optimize the cell culture, purification and conjugation processes, then transfer the conjugate to Dr. Ekaterina (Kate) Dadachova, a world renowned nuclear physicist who is Chair in Radiopharmacy at the University of Saskatchewan and Chair of the Scientific Advisory Board at Radimmune Therapeutics. Dr. Dadachova will lead the development and characterization of the radiolabeling process suitable for clinical studies. We have worked with Dr. Dadachova for more than 10 years on a variety of biopharmaceutical candidates, which have had a high level of success in animal and early to mid-stage human clinical trials."

About Radimmune

Radimmune Therapeutics is an early stage biotechnology company pioneering innovative therapies via its proprietary antibody drug conjugation platform for melanoma, pancreatic and other cancers. Since its inception, the Radimmune Therapeutics has been driven by the belief that additional tools are needed for the fight against cancer. To that end, Radimmune Therapeutics has developed a proprietary technology and platform focused on the most challenging to treat cancers. In recognition of the excellent potential displayed in early pre-clinical work, Radimmune Therapeutics was awarded an SBIR Grant by the NIH/NCI thereby validating much of the research to date. Radimmune Therapeutics continues to advance preclinical development programs with the goal of launching a Phase 1 clinical trial in 2019.

About Goodwin Biotechnology, Inc.

Goodwin Biotechnology is a uniquely qualified and flexible, US based 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 25 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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