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QSAM Biosciences Adds Rutgers Cancer Institute of New Jersey as Clinical Trial Site To Expand and Advance Study of CycloSam® in the Treatment of Bone Cancer

Austin, TX, Oct. 26, 2022 (GLOBE NEWSWIRE) -- QSAM Biosciences, Inc. (OTCQB: QSAM), a company developing next generation therapeutic radiopharmaceuticals, including Samarium-153-DOTMP (CycloSam®), for the treatment of bone cancer and related diseases and conditions, today announces the addition of Rutgers Cancer Institute of New Jersey (RCINJ) as a clinical trial site approved to begin enrolling patients into the Phase 1 study evaluating CycloSam® in treating patients with bone cancer that either originated in or has metastasized to the bone.

RCINJ is part of Rutgers Health and New Jersey's only National Cancer Institute (NCI) – designated Comprehensive Cancer Center, an elite recognition that is granted competitively to institutions based on their scientific leadership, resources, and outstanding track record of research discoveries and ability to translate these discoveries to benefit cancer patients. RCINJ is QSAM's second trial site approved to enroll patients in this study.

QSAM's study is a multiple center, dose escalation clinical trial intended to determine the maximum tolerated dose of CycloSam® in patients, and also assess early efficacy signals. Patients with bone cancer that has metastasized from the breast, prostate, lung, or other organs are eligible to enroll in the study. Additionally, osteosarcoma and Ewing's Sarcoma bone cancer patients, diseases that mostly affect children and young adults, are also eligible.

"The addition of Rutgers as our second clinical trial site will allow us to advance our study more rapidly in this major northeast population center," stated Douglas R. Baum, CEO. "We are pleased and honored to have the participation of the outstanding Rutgers CINJ team, who brings a substantial depth of knowledge and clinical development experience to our trials for CycloSam®."

"We look forward to being part of this important clinical trial evaluating this new and novel formulation of Samarium-153 as a therapeutic," stated Sanjay Goel, MD, Director of Phase I/Investigational Therapeutics and Medical Oncologist who will serve as the Investigator for the clinical trial site located in New Brunswick, NJ. "New treatment options for primary and metastatic bone cancer are very much needed and therapeutic radiopharmaceuticals such as CycloSam® offer potential benefits for these patients," Dr. Goel added.

Adults with bone cancer that has migrated or metastasized from the prostate, breast, or lung is common and frequently fatal. QSAM is dedicated to developing its Cyclosam® drug candidate for this important patient population to address this major unmet medical need, and patients with any of these bone cancer types are eligible for this clinical trial. Osteosarcoma, while still a rare pediatric disease, is the most common form of bone cancer in children and young adults (ages 15-39) with primary high-grade bone malignancy, and Ewing's Sarcoma bone cancer is the second most common form of bone cancer in children. According to the *Cancer Facts & Figures 2021* produced by the American Cancer Society, there are about 400,000 new cases of malignant bone metastasis and 3,610 new cases of primary bone cancer diagnosed in the United States each year.

About QSAM Biosciences

QSAM Biosciences, Inc. is developing next-generation nuclear medicines for the treatment of cancer and related diseases. QSAM's initial technology, CycloSam® (Samarium-153 DOTMP), is a clinical-stage bone-targeting radiopharmaceutical developed by IsoTherapeutics Group LLC, pioneers in the nuclear medicine space who also developed the FDA-approved Quadramet® (Samarium-153 EDTMP) radiopharmaceutical product, which is indicated for pain palliation. QSAM is led by an experienced executive team and board of directors that have completed numerous FDA approvals and multiple successful biotech exits.

CycloSam® has demonstrated preliminary safety and efficacy in animal studies and a single patient FDA-cleared human trial performed in 2020 at the Cleveland Clinic. This nuclear technology uses low specific activity Samarium-153 (resulting in far less long-lived europium impurities) and DOTMP, a chelator which is believed to reduce or eliminate off-target migration and targets sites of high bone turnover, making it, in management's opinion, an ideal agent to treat primary and secondary bone cancers. Since CycloSam® delivers targeted radiation selectively to the skeletal system and to bone tumors, it is also believed to be a candidate for effectiveness trials in bone marrow ablation as preconditioning for bone marrow transplantation, as well as in procedures to reduce external beam radiation to bone tumors. This multi-patented drug candidate utilizes a radioisotope previously approved by the FDA combined with a novel chelant, DOTMP, that has demonstrated preliminary increased efficacy and decreased side effects in animal models and veterinary treatment of bone cancer in dogs. Further, CycloSam® utilizes a streamlined, just-in-time manufacturing process that is already in place. Given these factors, management believes there is a strong pathway to commercialization for CycloSam®.

Legal Notice Regarding Forward-Looking Statements: This news release contains "forward-looking statements." These statements relate to future events or our future financial performance. These statements are only predictions and may differ materially from actual future results or events. We disclaim any intention or obligation to revise any forward-looking statements, whether as a result of new information, future developments or otherwise. There are important risk factors that could cause actual results to differ from those contained in forward-looking statements, including, but not limited to, our ability to fully commercialize our technology, risks associated with changes in general economic and business conditions, regulatory risks, clinical trial risks, early stage versus late-stage product safety and efficacy, actions of our competitors, the extent to which we are able to develop new products and markets, the time and expense involved in such development activities, the ability to secure

additional financing, the ability to consummate acquisitions and ultimately integrate them, the level of demand and market acceptance of our products, climate-related risks and changes in our business strategies. This is not an offering of securities, and securities may not be offered or sold absent registration or an applicable exemption from the registration requirements.

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