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QSAM Biosciences Recruits the Ellis Fischel Cancer Center at the University of Missouri as Clinical Trial Site to Further Expand and Advance the Study of CycloSam® for Bone Cancer

Austin, TX, Feb. 22, 2023 (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 the Ellis Fischel Cancer Center (EFCC) at the University of Missouri (MU) School of Medicine (SOM) as an upcoming clinical trial site to soon begin enrolling participants into the Phase 1 study evaluating CycloSam® for participants with multiple types of bone cancer that either originated in or has metastasized to the bone.

The Ellis Fischel Cancer Center is accredited as an Academic Comprehensive Cancer Program by the Commission on Cancer, an American College of Surgeons quality program. Ellis Fischel is QSAM's third clinical trial site to be approved for this study which is currently recruiting participants in New Jersey and Texas.

QSAM's study is a multiple center, open label, dose escalation clinical trial intended to determine the maximum tolerated dose of CycloSam® in participants, and also assess early efficacy signals. Participants with bone cancer that has metastasized from the breast, lungs, prostate or other organs, as well as participants with cancer that has originated in the bone such as osteosarcoma and Ewing's Sarcoma – diseases that mostly affect children and young adults -- are also eligible subject to the trial's inclusion and exclusion criteria.

"We are pleased and excited to bring on the team at the Ellis Fischel Cancer Center with their experience and resources to continue to advance our clinical development program for CycloSam®," stated Douglas R. Baum, CEO. "We are looking forward to their active participation in completing this clinical trial in 2023 and working with us on the next phase of development later this year."

"Primary and secondary metastatic bone cancer remains an area of high unmet medical need for individuals who have few and limited standard of care options and we support studies regarding potential new therapies," stated Gregory Biedermann, MD, a Radiation Oncologist who will serve as an Investigator for the clinical trial site located in Columbia, MO. "We look forward to being part of this important clinical trial evaluating the safety and early efficacy of CycloSam®, a new formulation of the therapeutic radiopharmaceutical Samarium-

153."

"This study is especially significant for the Ellis Fischel Cancer Center," stated Parvesh Kumar, MD, Associate Dean of Clinical and Translational Research for the MU SOM, and also the Associate Director of Clinical Sciences for the EFCC. "While we participate in many Phase II and III studies, this is the first Phase 1 radiopharmaceutical clinical trial for the EFCC. Phase 1 studies provide early availability of therapies from first in human studies to our participants, and they continue our leadership in translational research. We are excited to be part of this study because we recognize the growing significance of targeted radiotherapy for oligometastases".

Adults with bone cancer that has migrated or metastasized from the breast, lung or prostate is common and frequently fatal. QSAM is dedicated to developing its Cyclosam® product for this important population, and participants 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 targeting 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 radiopharmaceutical product Quadramet® (Samarium-153 EDTMP). The QSAM team has designed Cyclosam® with the goal of overcoming the clinical limitations of Quadramet®. 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 participant 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 great potential candidate for future effectiveness clinical trials in bone marrow ablation as preconditioning for bone marrow transplantation, as well as its future clinical trials 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®.

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