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QSAM Biosciences Opens Enrollment of the Second Cohort of Patients in its Phase 1 Study of CycloSam® Targeting Metastatic Bone Cancer

Austin, TX, April 05, 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 other diseases and conditions, today announces the opening of enrollment into the 2nd grouping of participants (Cohort 2) after completing Cohort 1 in February in its Phase 1 study evaluating CycloSam® in the treatment of bone cancer.

“We have met all criteria to continue patient enrollment at a higher dose level in the next group of patients,” stated Douglas R. Baum, CEO. “We are pleased with the safety data and early signs of efficacy, and we are now moving forward with three active clinical trial sites to continue to recruit, screen and enroll participants in this important study evaluating the safety and early efficacy of CycloSam® in patients with metastatic bone cancer."

QSAM’s study is a multiple-center, open label, dose escalation clinical trial intended to determine the maximum tolerated dose of CycloSam® in patients, and also assess early safety and efficacy signals. The total dosage of the active radioisotope Samarium-153 to be received by participants in the second cohort is 50% higher than the total dose received by participants in the first cohort.

Mr. Baum continued: “With almost $3 million in funding received in our recently completed private placement, and conversion of all of our outstanding convertible notes into common stock, QSAM is in a much stronger position to advance our clinical trials, achieve several important milestones this year, and create a solid foundation for growth and value creation.”

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 patient population, 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 (which includes approximately 14% of the 265,000 women diagnosed with breast cancer each year), 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. The QSAM team has designed the Cyclosam® product with the goal of overcoming the limitations of the Quadramet® (Samarium-153 EDTMP) product FDA-approved indications. 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 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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