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QSAM Biosciences Receives Clearance from FDA to Expand Enrollment Criteria in its Phase 1 Study of CycloSam® Targeting Metastatic Bone Cancer

Austin, TX, March 08, 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 that the U.S. Food & Drug Administration (FDA) has cleared the Company's amended clinical trial protocol increasing the maximum age of participants to 75 years old from the prior age limitation of 65. This amendment to the enrollment criteria significantly expands the population of potential participants in QSAM's Phase 1 study evaluating CycloSam® in the treatment of bone cancer.

The prevalence of bone metastases in patients over age 70 is greater than 30% among breast cancer patients and almost 50% for prostate cancer patients, according to recently published literature from the NIH SEER database (Surveillance, Epidemiology, and End Results). Older patients comprise a significant percentage of the current population of patients with metastatic bone cancer that is targeted by the CycloSam® drug product. The FDA encourages sponsors to enroll participants who reflect the characteristics of clinically relevant populations, including age and sex, to allow for the collection of sufficient information pertaining to safety and effectiveness for product labeling.

"There is an urgent and immediate unmet need for patients over 65 years old with cancer that has metastasized to the bone," stated Julio Peguero, M.D., a board certified in Internal Medicine and Medical Oncology Subspecialty physician who has treated the first three participants in QSAM's clinical trial. "Safety data from our initial patients in this clinical trial show no serious adverse events (SAE's) and no clinically significant adverse events that suggest the CycloSam® drug product would create a safety issue for older patients who make up a large percentage of the bone metastasis cases we see. We look forward to continuing the study with this important population."

Douglas Baum, CEO of QSAM stated: "We thank the FDA for clearing our amended clinical trial protocol, which should allow us to accept a greater percentage of the participants screened for enrollment, and as a result, move the study ahead more quickly and efficiently. Our mission at QSAM is making sure the broadest possible population fighting this deadly disease may one day be able to benefit from CycloSam®."

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's 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®.

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, inflation and recession risks, 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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