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QSAM Biosciences Activates Clinical Sites and Opens Enrollment for its Phase 1 Clinical Trial of CycloSam® for the Treatment of Bone Cancer

Austin, TX, Dec. 01, 2021 (GLOBE NEWSWIRE) -- QSAM Biosciences Inc. (OTCQB: QSAM), a company developing next-generation therapeutic radiopharmaceuticals, including Samarium-153-DOTMP (CycloSam®), for the treatment of cancer and related diseases, today announces the activation of its first clinical trial site and the initiation of enrollment of patients into its Phase 1 clinical trial evaluating CycloSam® for multiple types of bone cancer that either originated in or has metastasized to the bone. The Company's initial enrollment site is at Oncology Consultants in Houston, TX.

The Phase 1 multi-center dose escalation trial is designed to determine the maximum tolerated dose of CycloSam® in patients, with the additional goal of assessing early efficacy markers. Patients with bone cancer that has migrated or metastasized from the prostate, breast, lung or other organs are eligible for enrollment. According to the American Cancer Society there are about 400,000 new cases of malignant bone metastasis diagnosed in the United States each year.

Osteosarcoma and Ewing's Sarcoma patients are also eligible for enrollment in the trial. Osteosarcoma 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. There have been very few advancements in treating these primary bone cancers for over 40 years, and in August 2021, CycloSam® received Orphan Drug Designation from the FDA for the treatment of osteosarcoma.

"The initiation of our first Phase 1 clinical trial of CycloSam is an important development for QSAM as it demonstrates the potential for treating bone cancers using our new approach. We look forward to driving enrollment forward and establishing a safety profile and understanding of CycloSam's potential for efficacy," stated Douglas R. Baum, QSAM's CEO.

"We are pleased to be participating in this clinical trial studying this innovative formulation of Samarium-153," added Julio A. Peguero, M.D., Director of Research for Oncology Consultants, who will serve as the Investigator for the clinical trial site located in Houston, TX. "Therapeutic radiopharmaceuticals like CycloSam may represent a potentially important treatment option for patients suffering from metastatic bone cancer."

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 and commercially available 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 dozens of 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 in the Cleveland Clinic. This nuclear technology uses low specific activity Samarium-153 (resulting in far less europium) and DOTMP, a chelator which is believed to eliminate off-target migration and targets sites of high bone turn over 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, it is also believed to be an effective agent to perform bone marrow ablation as pre-conditioning for bone marrow transplantation, and in procedures to reduce external beam radiation to bone tumors. This multi-patented drug candidate utilizes an FDA approved radioisotope combined with a novel chelant 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®.

About Oncology Consultants
Oncology Consultants has been a premier adult medical oncology and hematology practice in Houston, Texas for over 37 years, established since 1982. Our healthcare team is committed to provide state of the art cancer treatment in a caring environment as we continue to expand our oncology services in Texas.

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, 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, 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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