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QSAM Biosciences Expands its Study of CycloSam® in the Treatment of Bone Cancer; Opens Patient Enrollment at Key Chicago Center, Insight Hospital and Medical Center

Austin, TX, May 23, 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 addition of the [Insight Research Institute](#) at the [Insight Hospital and Medical Center](#) in Chicago, IL, as a clinical trial site approved to begin enrolling participants into the Phase 1 study evaluating CycloSam® in patients with multiple types of bone cancer that either originated in or has metastasized to the bone.

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

"We are pleased to be working with the excellent team at Insight Hospital and Medical Center to continue the expansion of our drug development program for CycloSam® in the large population center of Chicago," stated Douglas R. Baum, CEO and co-founder of QSAM. "We expect the addition of this fourth clinical trial site will help advance our study, and it also constitutes the initial site that will be serviced through our recently announced partnership with the leading nuclear pharmacy network, Radioisotope Life Sciences, [RLS](#)."

"Metastatic bone cancer is often life threatening and remains an area of high unmet medical need for patients with limited treatment options that are often ineffective," stated Mohammed T. Hussain, MD, an Oncologist and the Investigator at Insight Hospital and Medical Center. "Therapeutic radiopharmaceuticals like CycloSam® represent a novel and potentially important treatment option for patients suffering from this debilitating and deadly disease."

About QSAM Biosciences

QSAM Biosciences, Inc. is developing next-generation nuclear medicines for the treatment of cancer and other 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), which is indicated for bone cancer 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[®] is currently being studied in an open-label, dose escalating Phase 1 safety study at four clinical trial sites in the United States, with a focus on bone cancer that has metastasized from the breast, lung, prostate or other organs. The drug candidate has demonstrated preliminary safety and efficacy in animal studies and a single patient FDA-cleared human trial performed in 2020 at the Cleveland Clinic. QSAM has also received Orphan Drug and Rare Pediatric Disease Designations from the FDA for the indication of osteosarcoma, a disease that mostly affects children and young adults.

CycloSam[®] uses a patented formulation of low specific activity Samarium-153 (resulting in far less long-lived europium impurities) and DOTMP, a chelator that targets sites of high bone turnover and is believed to reduce or eliminate off-target migration, making it, in management's opinion based on scientific data, an ideal agent to treat primary and secondary bone cancers. Through the carrier vehicle DOTMP, CycloSam[®] delivers targeted radiation selectively to the skeletal system with high uptake adjacent to areas of bone tumors where the beta-emitting Samarium-153 can irradiate and potentially destroy cancer cells. Because of CycloSam's mechanism of action and demonstrated safety profile to date, it is also believed to be a candidate for effectiveness trials in bone marrow ablation as preconditioning for stem cell transplantation, as well as in procedures to reduce external beam radiation to bone tumors. Further, CycloSam[®] utilizes a streamlined, just-in-time manufacturing process that is already significantly 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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