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QSAM Biosciences Receives Orphan Drug Designation from FDA for CycloSam® in the Treatment of Osteosarcoma

Austin, TX, Aug. 18, 2021 (GLOBE NEWSWIRE) -- QSAM Biosciences Inc. (OTCQB: QSAM), a company developing next generation nuclear medicines, including Samarium-153-DOTMP (CycloSam®), for the treatment of cancer and related diseases and conditions, announced that the U.S. Food and Drug Administration (FDA) has approved QSAM's application for Orphan Drug Designation of CycloSam® in the treatment of patients diagnosed with osteosarcoma.

Osteosarcoma is the most common form of bone cancer in children and young adults (ages 15-39) with primary high-grade bone malignancy. Out of five patients who develop or present with metastatic osteosarcoma bone cancer, only one will survive. There have been few advancements over the last 40 years for this deadly disease, and accordingly, there is a large unmet market need for a better treatment that is more efficacious against pediatric osteosarcoma and better tolerated by patients.

"Receipt of Orphan Drug Designation is an important accomplishment for our bone cancer program and for our company. This designation further validates our data-driven approach in oncology drug development and sets the stage for additional aggressive efforts we are undertaking in pediatric and adult cancer therapies," stated the Company's CEO, Douglas R. Baum. "Orphan Drug Designation is designed to provide a number of benefits, most notably, seven years of market exclusivity, which complements our growing portfolio of issued patents that we expect will provide us enhanced commercial and market protections."

Baum continued: "This orphan designation is one of several milestones we have achieved since we started last year working to bring CycloSam through the clinical trial process and ultimately, with FDA approval, to market. We are excited to advance this groundbreaking research to help patients suffering from this devastating disease where the benefits of current treatment options are very limited."

CycloSam is believed to be a significantly improved formulation of a previously FDA approved radiopharmaceutical. This novel drug candidate utilizes both a more efficient method of isotope manufacturing and an advanced chelation technology which may potentially allow for repeated dosing of patients with bone cancer in an effort to halt or reverse tumor growth.

About QSAM Biosciences:

QSAM Biosciences, Inc. is developing next-generation nuclear medicines for the treatment of cancer and related diseases. QSAM's initial technology is CycloSam® (Samarium-153

DOTMP), a clinical-stage bone targeting radiopharmaceutical developed by IsoTherapeutics Group LLC, pioneers in the nuclear medicine space who also developed a previous FDA-approved and commercially available radiopharmaceutical product 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 successfully performed in 2020. This nuclear technology uses low specific activity Samarium-153 (resulting in far less europium-154 impurity) and DOTMP, a chelator which is believed to eliminate off-target migration and targets sites of high bone turn over making it an ideal agent to treat primary and secondary bone cancers. Since CycloSam® has the ability to deliver 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®.

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, 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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