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# QSAM Biosciences Doses First Patient in its Clinical Trial for CycloSam<sup>®</sup>, Radiopharmaceutical Drug Candidate for the Treatment of Bone Cancer

Austin, TX, April 28, 2022 (GLOBE NEWSWIRE) -- [QSAM Biosciences Inc.](#) (OTCQB: QSAM), a company developing next-generation therapeutic radiopharmaceuticals, including Samarium-153-DOTMP (CycloSam<sup>®</sup>), for the treatment of bone cancer and related diseases, announces today that the first patient commenced treatment in its clinical trial evaluating CycloSam<sup>®</sup> in patients with metastatic bone cancer.

QSAM previously announced the clearance of its IND by the U.S. Food and Drug Administration (FDA) and activation of clinical trial sites in its multi-center clinical trial for patients with bone cancer, including cancer that has metastasized from the lung, breast or prostate. Patients with cancer that originated in the bone including osteosarcoma and Ewing's sarcoma are also eligible to participate. The study is a Phase 1 open-label, dose-escalation trial to evaluate the safety, tolerability, dosimetry, and preliminary efficacy of CycloSam<sup>®</sup>.

"This is an important milestone for QSAM. Successfully treating patients with primary or secondary bone cancer remains an area of significant unmet medical need and a goal for CycloSam<sup>®</sup>. Every day our teams are working toward developing CycloSam<sup>®</sup> as a breakthrough therapeutic for cancer patients, both children and adults, male and female, who unfortunately still have poor options and limited long term survival prognosis," stated Douglas R. Baum, CEO and co-founder of the Company. "We look forward to sharing the results of this study with our shareholders and the medical community."

## 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<sup>®</sup> (Samarium-153 DOTMP), is a clinical-stage bone targeting radiopharmaceutical developed by IsoTherapeutics Group LLC, pioneers in the nuclear medicine space who also developed other FDA-approved radiopharmaceutical products. QSAM is led by an experienced executive team and Board of Directors that completed numerous FDA approvals and multiple successful biotech exits.

CycloSam<sup>®</sup> demonstrated preliminary safety and efficacy in animal studies and a single patient FDA-cleared human trial performed in 2020 at the Cleveland Clinic. This radiopharmaceutical technology uses low specific activity Samarium-153 (resulting in far less undesirable europium impurity) and DOTMP, a chelator which the Company believes

reduces or eliminates off-target migration, targets sites of high bone turn over, and makes it an ideal agent to treat primary and secondary bone cancers. Because CycloSam<sup>®</sup> delivers targeted radiation selectively to the skeletal system, the Company also believes it is an important candidate for use in 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 a radioisotope previously approved by the FDA combined with a novel targeting chelant that demonstrated preliminary increased efficacy and decreased side effects in animal models and veterinary treatment of bone cancer in dogs. Further, CycloSam<sup>®</sup> utilizes a well-established, streamlined, just-in-time manufacturing process.

**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, supply chain risks, 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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