

QSAM Biosciences Receives Second Key Patent in Europe for its Clinical Stage Radiopharmaceutical Drug Candidate, CycloSam®

Austin, TX, April 26, 2023 (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 other diseases, announced today that the European Patent Office (EPO) has allowed a key patent that protects the use of "lower specific activity" Samarium-153 in conjunction with the treatment of bone cancer in children and adults.

This new patent in Europe covers the "high purity therapeutic bone agents" technology exclusively licensed to QSAM on a worldwide basis and relates to the novel manner in which the Samarium-153 is produced for use in CycloSam[®]. In addition to providing streamlined manufacturing, lower costs and logistical advantages, that process significantly reduces long-lived impurities, namely Europium-154, which may allow for higher and multiple dosing regimens in the treatment of different types of bone cancer, including cancer that has metastasized from the breast, lung, prostate, kidney or other organs. These types of metastasized bone cancer are the subject of QSAM's current FDA-cleared Phase 1 clinical trial which is underway and actively enrolling and dosing patients.

"We believe that repeated dose regimens of CycloSam[®] may be the key to being able to successfully treat bone tumors, and we are continuing to advance our clinical trials program to generate data toward that goal," stated Douglas R. Baum, CEO and co-founder of the Company.

"This allowance by the EPO marks our second patent in Europe, and we expect to register the patent in multiple individual countries in the EU over the following few weeks, thereby expanding our already established and robust patent estate. More so, this additional IP protection broadens our potential commercial market for what we believe may eventually be a breakthrough therapy for both primary and secondary forms of bone cancer," added Mr. Baum.

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) radiopharmaceutical product. The

QSAM team has designed the Cyclosam[®] product with the goal of overcoming the limitations of the Quadramet[®] (Samarium-153 EDTMP) product and potentially expand the 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, CvcloSam® 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[®].

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Source: QSAM Biosciences Inc.