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QSAM Biosciences and RLS Announce Clinical and Commercial Supply Agreement for Promising Clinical-Stage Metastatic and Primary Bone Cancer Treatment, CycloSam®

Partnership is Latest in Series of RLS Efforts to Expand Industry-Leading CDMO Business and Clinical Trial Capability with Radiopharmaceutical Partners Across U.S.

Austin, TX and Lake Zurich, IL, May 16, 2023 (GLOBE NEWSWIRE) -- QSAM Biosciences, Inc. (OTCQB: QSAM), a clinical stage biotechnology company developing next-generation therapeutic radiopharmaceuticals, and **RLS (USA) Inc.**, the third-largest nuclear medicine pharmacy network in the U.S., announced today a commercial supply and clinical dose preparation agreement for the therapeutic radiopharmaceutical drug candidate CycloSam® (Samarium-153 DOTMP), a promising clinical-stage treatment for metastatic and primary bone cancer in adults and children.

QSAM is actively enrolling patients with metastatic bone cancer in a Phase I clinical trial for CycloSam® across three clinical sites in the United States with additional sites planned. The RLS agreement allows for the rapid and efficient preparation of CycloSam® doses, under strict industry quality control systems, for patient administration in the current and future clinical trials with an option to expand to commercial scale if CycloSam® is ultimately approved by the FDA.

“We believe the short half-life of Samarium-153 with respect to patient exposure, toxicity and tolerability makes it an ideal drug to treat bone cancers. The ability to meet the potential demand requires a pharmacy network capable of preparing and timely delivering patient doses for administration,” said Douglas R. Baum, CEO and co-founder of QSAM. “The RLS network of 31 radiopharmacies across 18 states adds significant geographic coverage and infrastructure to our supply chain, along with an unprecedented level of on-the-ground expertise and credibility as the only accredited radiopharmacy network in the country. Choosing RLS as a partner will not only bolster our current and near-term clinical trials, but it may also provide the initial groundwork for eventual commercial supply and distribution.”

Samarium-153 (Sm-153) is a beta-emitting radioisotope that carries radiation designed and intended to disrupt tumor cell metabolism and cause cancer cell death. With a short 46-hour radiation half-life, Sm-153, in combination with the bone-seeking chelant DOTMP that significantly limits unwanted off-target migration of radiation to nearby healthy tissues, represents a potentially highly effective bone cancer treatment. The RLS agreement is

expected to support QSAM's clinical research and potential future commercial use of CycloSam®.

Stephen Belcher, CEO of RLS, added, "RLS is proud to partner with the talented management team at QSAM in support of these important clinical trials. With this announcement, we are deepening our commitment to building a world-class CDMO and clinical trial business and serving as a trusted, reliable partner for companies like QSAM developing the next-generation of nuclear therapies."

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 Quadramet® 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 highly targeted and actively drawn to areas of high bone turnover, making it, in management's opinion based on scientific studies, 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, 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 RLS (USA) Inc.

RLS (USA) Inc., the third-largest nuclear medicine pharmacy network in the United States, owns and operates 31 radiopharmacies across 18 states, offering an extensive portfolio of molecular imaging products. We endeavor to supply the highest quality radiopharmaceuticals in the industry by dispensing 100 percent of injectable unit dose products in clean rooms built to ISO 1644-1 specifications. In support of our commitment to quality, we provide tailored solutions and exceptional service to our more than 1500 customers. For more information, please visit www.rls.bio.

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"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, inflation and recession risks, 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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Source: QSAM Biosciences Inc.