The pharma& Group Enters into an Exclusive Promotional Agreement with Tolmar, Inc. to Promote Rubraca® (rucaparib) in the U.S. for the Treatment of Metastatic Castration-Resistant Prostate Cancer

Intended for the Media

Vienna, Austria, and Buffalo Grove, Ill., September 24, 2024 – pharmaand GmbH (pharma&) and Tolmar, Inc. (Tolmar) announced today an exclusive agreement for Tolmar to promote Rubraca (rucaparib) in the U.S. for the treatment of metastatic castration-resistant prostate cancer (mCRPC). pharma& will continue to promote Rubraca in the U.S. and Europe in approved indications for advanced ovarian cancer.

Under the terms of the Agreement, Tolmar will be responsible for U.S. marketing and sales activities to promote Rubraca in mCRPC. pharma& will be responsible for U.S. supply of product and regulatory responsibilities, including product labeling for Rubraca in mCRPC and retains the global rights to Rubraca.

"We are pleased to have finalized our Agreement with Tolmar to provide commercial support for Rubraca in the U.S. for the treatment of metastatic castration-resistant prostate cancer," said Frank Rotmann, Founder and Managing Director of pharma&. "We are confident that partnering with Tolmar will further expand the use of Rubraca to eligible patients with mCRPC."

"We are excited to add Rubraca to our Prostate Cancer Portfolio in the U.S.," said Anil D'Souza, CEO of Tolmar, Inc. "Along with our flagship advanced prostate cancer treatment Eligard, we are now building on that foundation of care with Rubraca. Tolmar is proud of its dedication to patients, healthcare providers, and the Urology-Oncology community. We look forward to providing Rubraca as an option for eligible men with mCRPC."

Rubraca® (rucaparib) U.S. Prostate Cancer FDA Approved Indication

Rubraca is indicated for the treatment of adult patients with a deleterious BRCA mutation (germline and/or somatic)-associated metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor-directed therapy and a taxane-based chemotherapy. This indication is approved under accelerated approval based on objective response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

Select Important Safety Information

Myelodysplastic Syndrome (MDS)/Acute Myeloid Leukemia (AML) have occurred in patients treated with Rubraca, and are potentially fatal adverse reactions. In TRITON2, MDS/AML was not observed in patients with mCRPC (n=209) regardless of homologous recombination deficiency (HRD) mutation.

Do not start Rubraca until patients have recovered from hematological toxicity caused by previous chemotherapy (≤ Grade 1). Monitor complete blood counts for cytopenia at baseline and monthly thereafter for clinically significant changes during treatment. For prolonged hematological toxicities (> 4 weeks), interrupt Rubraca or reduce dose and monitor blood counts weekly until recovery. If the levels have not recovered to Grade 1 or less after 4 weeks or if MDS/AML is suspected, refer the patient to a hematologist for further investigations, including bone marrow analysis and blood sample for cytogenetics. If MDS/AML is confirmed, discontinue Rubraca.

Based on its mechanism of action and findings from animal studies, Rubraca can cause fetal harm when administered to a pregnant woman. Apprise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment and for 6 months following the last dose of Rubraca.

For males on Rubraca treatment who have female partners of reproductive potential or who are pregnant, effective contraception should be used during treatment and for 3 months following the last dose of Rubraca. Advise male patients on Rubraca treatment, who have female partners of reproductive potential or who are pregnant to use effective contraception during treatment and for 3 months following the last dose of Rubraca.

Most common adverse reactions in patients with BRCA-mutated mCRPC in TRITON2 (≥ 20%; Grade 1-4) were fatigue/asthenia (62%), nausea (52%), anemia (43%), AST/ALT elevation (33%), decreased appetite (28%), rash (27%), constipation (27%), thrombocytopenia (25%), vomiting (22%), and diarrhea (20%).

Co-administration of rucaparib can increase the systemic exposure of CYP1A2, CYP3A, CYP2C9, or CYP2C19 substrates, which may increase the risk of toxicities of these drugs. Adjust dosage of CYP1A2, CYP3A, CYP2C9, or CYP2C19 substrates, if clinically indicated. If co-administration with warfarin (a CYP2C9 substrate) cannot be avoided, consider increasing frequency of international normalized ratio (INR) monitoring.

Because of the potential for serious adverse reactions in breast-fed children from Rubraca, advise lactating women not to breastfeed during treatment with Rubraca and for 2 weeks after the last dose.

Please Click here for full Prescribing Information for Rubraca.

For medical information inquiries within the U.S., contact pharma& at medinfo.us@pharmaand.com.

You may report adverse events to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Alternatively, to report an adverse event or reaction, contact pharma& at pv@pharmaand.com.

To report a product complaint, contact pharma& at complaints@pharmaand.com.

Eligard® (leuprolide acetate) for injectable suspension Indication

Eligard is used for the palliative treatment of advanced prostate cancer. Eligard is a prescription medication that must be administered by a health care professional.

Important Safety Information

Eligard should not be used by anyone who is allergic to any of the ingredients in Eligard or to any similar drugs.

Eligard causes an increase in testosterone during the first few weeks of therapy and some men may experience new or worsening symptoms of prostate cancer e.g., bone pain, urinary symptoms, or nerve problems such as numbness, during this period. If your cancer has spread to the urinary tract or spine, urinary blockage or pressure on the spine that can lead to paralysis may occur. Your doctor will discuss with you the benefits and risks of taking Eligard.

Increased risk of heart attack, sudden death due to heart problems and stroke have also been reported in men taking Eligard. Eligard may also affect electrical activity in the heart that can cause an irregular heartbeat. Your doctor will monitor you for heart conditions.

Elevated blood sugar and an increased risk of developing diabetes have been reported in men receiving Eligard. Your doctor will monitor blood sugar levels. Convulsions have been observed in patients taking leuprolide acetate, including patients who have a history of seizures, epilepsy, or brain disorders (related to blood vessels, nerves, or tumors), and in those taking medications associated with convulsions. Convulsions have also been reported in patients without any of these conditions.

Eligard may cause fetal harm when administered to a pregnant woman. Expected hormonal changes that occur with Eligard treatment increase the risk for pregnancy loss.

Eligard may impair fertility in males of reproductive potential. The most common injection site reactions are transient burning and stinging, pain, bruising, and redness. The most common side effects include hot flashes/sweats, fatigue, weakness, muscle pain, dizziness, clamminess, testicular shrinkage, decreased erections and enlargement of breasts.

Other side effects, including thinning of bones that may lead to fracture, and rare but serious problems with the pituitary gland in the brain, have been reported with Eligard.

Call your doctor for medical advice about side effects. You may report side effects to the FDA.

Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please Click here for full Prescribing Information for Eligard

For medical information inquiries within the U.S., contact Tolmar at tolmarproductsupport@tolmar.com

You may report adverse events to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

Alternatively, to report an adverse event or reaction or to report a product complaint, contact Tolmar at 1-844-4TOLMAR

About pharma& (www.pharmaand.com)

pharmaand GmbH (pharma&), a privately owned global company, aspires to breathe new life into proven medicines. The Company is dedicated to preserving the availability and fostering the further development of essential medicines worldwide to leave no patient behind. Over the past five years, pharma& has acquired and integrated 10+ medicines, expanding its portfolio across a wide range of therapy areas, with an increasing focus on hematology and oncology treatments. The Company's unique synthesis of subsidiaries, joint ventures, and partners enables pharma& to provide its portfolio of medicines to eligible patients worldwide by spanning the continuum of development, product and API manufacturing, partner distribution, healthcare provider engagement, distribution and services to patients.

pharma& cautions that any forward-looking statements or projections made, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. pharma& does not undertake to update or revise any forward-looking statements.

About Tolmar Inc.

Tolmar is a fully integrated specialty pharmaceutical company focused on the development, manufacturing, and commercialization of specialty pharmaceuticals across multiple therapeutic areas, including Oncology, Urology, and Endocrinology. Tolmar's product development and manufacturing facilities are based in Northern Colorado and its executive offices and commercial headquarters are based in Buffalo Grove, Illinois. For more information about the company, please visit www.tolmar.com.

Tolmar cautions that any forward-looking statements or projections made, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Tolmar does not undertake to update or revise any forward-looking statements.

# # #

pharma& Media Contact:
media@pharmaand.com

Tolmar Media Contact:
info@tolmar.com