pharma& Announces Review Classification for supplemental New Drug Application (sNDA) Accepted by U.S. FDA for Rubraca® (rucaparib) Treatment of Chemotherapy-Naïve Metastatic Castration-Resistant Prostate Cancer

Intended for the Healthcare Media

Vienna, Austria, and Buffalo Grove, Ill., May 21, 2025 – pharmaand GmbH (pharma&) announced today it received confirmation that the U.S. Food and Drug Administration (FDA) has accepted the company's supplemental New Drug Application (sNDA) for Rubraca® (rucaparib) in the chemotherapy-naïve metastatic castration-resistant prostate cancer (mCRPC) setting. In addition, under the Prescription Drug User Fee Act (PDUFA), the FDA has assigned a target action date of January 12, 2026.

"We are pleased that the FDA has accepted the sNDA as it is an important milestone to bring Rubraca to eligible patients with Metastatic Castration-Resistant Prostate Cancer earlier in their treatment journey," said Frank Rotmann, Co-Founder and Managing Director of pharma&. "We appreciate the opportunity to work with the FDA in the coming months as they review the application to support this label expansion and further Tolmar's U.S. activities to promote Rubraca in mCRPC."

Under an exclusive agreement, Tolmar is responsible for promoting Rubraca in the U.S. for the treatment of mCRPC.

"This confirms our commitment to men's health and to our growing oncology pipeline," said Dr. Anjan Chatterjee, Chief Medical Officer of Tolmar Inc.

The supplement application to the FDA was based on the positive results from the TRITON3 study (NCT02975934), a Phase 3, multicenter, open-label, randomized trial of Rubraca in patients with chemotherapy-naïve mCRPC. The study enrolled 405 patients with a mutation in *BRCA* or *ATM* who were randomized to Rubraca or the control group, which consisted of physician's choice of docetaxel, abiraterone acetate, or enzalutamide. Approximately 55% of the patients in the control arm received docetaxel. The primary endpoint was radiographic progression-free survival(rPFS) by independent radiology review (IRR), in patients with mutations in *BRCA1, BRCA2* or *ATM*. TRITON3 was designed as a Phase 3 trial to confirm and expand the efficacy data from TRITON2 in an earlier treatment setting in mCRPC against a relevant control arm. Patients were selected for therapy based on an FDA-approved companion diagnostic for Rubraca.

About Prostate Cancer

The American Cancer Society estimates that approximately 314,000 men in the U.S. will be diagnosed with prostate cancer in 2025. Prostate cancer is the most common cancer, and the second most common cause of cancer-related mortality, among U.S. men.[1] It is estimated that

in 2023 in the U.S., there were more than 34,000 deaths from prostate cancer, representing 29% of all male cancer cases and 11% of all cancer deaths among men.[1] From 2014 to 2020, the five-year survival rate for patients with distant metastasis at diagnosis is 37%.[1] Prostate cancer often progresses from localized to mCRPC, which can be resistant to standard androgen-deprivation therapies and associated with mortality. Men with prostate cancer and a germline mutation in *BRCA2* typically develop mCRPC at a younger age, have more aggressive features, and higher mortality rates.[2] While less common in prostate cancer, germline mutations in *BRCA1* are also associated with more aggressive disease.

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.

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.

About pharma& (pharmaand.com)

pharmaand GmbH (pharma&), a privately owned global company, aspires to breathe new life into proven medicines through an agile and fully integrated business model, and aims to guarantee the enduring availability, dependability, and quality of essential drugs worldwide that patients and healthcare providers rely on. 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.com)

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.

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

References

[1] Surveillance, Epidemiology, and End Results, National Cancer Institute. Cancer Stat Facts: Prostate Cancer. Available at: https://seer.cancer.gov/statfacts/html/prost.html Accessed March 2025.

[2] Castro et al. Germline BRCA mutations are associated with higher risk of nodal involvement, distant metastasis, and poor survival outcomes in prostate cancer. Journal of Clinical Oncology. Available at: https://ascopubs.org/doi/10.1200/JCO.2012.43.1882 Accessed April 2025.