pharma&'s Rubraca® (rucaparib) Demonstrates Therapeutic Benefit for Eligible Patients with Advanced Ovarian Cancer Regardless of HRD Status

- *Across all exploratory post-progression evaluations for patients with homologous recombination deficiency (HRD)-negative and HRD-unknown tumors in the ATHENA-MONO clinical trial, the trend of benefit with rucaparib was consistent[1].*
- *This data suggests rucaparib benefit continues beyond completion of treatment in these patients[1].*
- *Median dose intensity for rucaparib was maintained for these subgroups as well as for the overall safety population[1].*
- *The safety profile of rucaparib in these patient groups was similar to that of the overall safety population[1].*

Intended for the Healthcare Media

Vienna, Austria, February 27, 2026 - pharmaand GmbH (pharma&) announced today data presented from the randomized, Phase 3 company-sponsored ATHENA trial investigating rucaparib monotherapy versus placebo (ATHENA-MONO) during a poster session at the European Society Gynaecological Oncology (ESGO)'s 27th European Gynaecological Oncology Congress in Copenhagen, Denmark.

Dr. Vanda Salutari, Gynecology Oncology Unit, Gemelli Polyclinic Foundation, IRCCS, Rome, Italy, on behalf of lead author Dr. Flora Zagouri, Aretaieio Hospital, National and Kapodistrian University of Athens School of Medicine, Athens, Greece, and ATHENA investigators, presented the poster "Rucaparib maintenance in ATHENA-MONO (GOG3020/ENGOT-ov45) in patients with newly diagnosed advanced ovarian cancer: exploratory post-progression evaluations for patients with homologous recombination deficiency (HRD)-negative and HRD-unknown tumors."

"The data presented further characterizes first-line rucaparib maintenance treatment with post-progression data for eligible patients with HRD-negative and HRD-unknown tumors," said Dr Vanda Salutari, Gynecology Oncology Unit, Gemelli Polyclinic Foundation, IRCCS, Rome, Italy. "Rucaparib may prolong progression-free survival and delay the need for subsequent therapies in a broad population of eligible patients with advanced ovarian cancer."

Progression-Free Survival (PFS) in HRD-Negative and HRD-Unknown Subgroups

In the ATHENA-MONO (NCT03522246) clinical trial, first-line rucaparib maintenance treatment provided a progression-free survival (PFS) benefit versus placebo in newly diagnosed, advanced, high-grade ovarian cancer after front-line platinum-based chemotherapy[2,3].

In the ATHENA-MONO trial, 44% of patients had HRD-negative disease (*BRCA*–wild-type with low loss of heterozygosity (LOH)), which represents a higher risk population with fewer treatment options than those with *BRCA*-mutated or HRD-positive tumors[1]. In addition, in the ATHENA-MONO trial, 12% of patients had an HRD-unknown status[1].

In these exploratory analyses, the benefit of rucaparib was consistent, prolonging chemotherapy-free interval (CFI), time to first subsequent treatment (TFST), second event of progression (PFS2), and time to second subsequent treatment (TSST) by 4 to 8 months compared with placebo in the HRD-negative and HRD-unknown groups[^1].

	Events/N (%)			
	Rucaparib	**Placebo**	**Median (Mo)[a]**	**HR (95% CI)[b]**
HRD-negative subgroup (*BRCA* wild-type/LOH^{10w})				
CFI	138/189 (73)	42/49 (86)	18.8 vs. 11.7	0.59 (0.42-0.83)
TFST	140/189 (74)	42/49 (86)	16.2 vs. 10.4	0.60 (0.42-0.84)
PFS2	125/189 (66)	41/49 (84)	24.4 vs. 19.3	0.66 (0.46-0.94)
TSST	124/189 (66)	41/49 (84)	28.9 vs. 21.4	0.63 (0.44-0.90)
HRD-unknown subgroup (*BRCA* wild-type/ LOH^{unknown})				
CFI	38/53 (72)	12/13 (92)	22.6 vs. 14.2	0.49 (0.25-0.93)
TFST	38/53 (72)	12/13 (92)	21.3 vs. 12.0	0.44 (0.23-0.86)
PFS2	33/53 (62)	10/13 (77)	35.0 vs. 30.6	0.71 (0.35-1.42)
TSST	34/53 (64)	10/13 (77)	35.1 vs. 31.2	0.72 (0.36-1.45)

Data cutoff: 5 May 2025
a. Kaplan-Meier analysis, rucaparib vs. placebo
b. Cox Proportional Hazard, unstratified. rucaparib vs. placebo

Median dose intensity of rucaparib for the HRD-negative and HRD-unknown groups was 87% and 81%, respectively, and was 89% for the overall safety population[1].

The safety profile of rucaparib in these patient groups was similar to that of the overall safety population.

Based on today's presentation, across all exploratory post-progression evaluations for patients with HRD-negative and HRD-unknown tumors in the ATHENA-MONO clinical trial, the trend of benefit with rucaparib was consistent, suggesting that rucaparib benefit continues beyond completion of treatment in these patients[1]. Median CFI ,TFST, PFS2, and TSST trended longer for rucaparib versus placebo in patients with HRD-negative and HRD-unknown tumors[1].

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^Definitions - *Chemotherapy-free interval (CFI): The time since the last dose of the most recent chemotherapy regimen to the date of the first dose of a subsequent chemotherapy, or death due to any cause. Time to first subsequent treatment (TFST): The time from randomization to the date of the first dose of the first subsequent anticancer treatment regimen, or death due to any cause. Second event of progression (PFS2): The time from randomization to the second event of disease progression as assessed by the investigator, or death due to any cause. Time to second subsequent treatment (TSST): The time from randomization to the date of the first dose of the second subsequent anticancer treatment regimen, or death due to any cause.*

"The data presented during the ESGO congress reinforces rucaparib's place as an important first-line maintenance treatment in advanced ovarian cancer across a broad patient population," said Frank Rotmann, Co-Founder and Managing Director, pharma&. "The results demonstrate that rucaparib continues to deliver benefit beyond the treatment period of this well-tolerated therapy, regardless of a patient's HRD status. We are proud to advance research that supports meaningful outcomes for patients."

About the ATHENA Clinical Trial

ATHENA (GOG 3020/ENGOT-ov45) (NCT03522246) is an international, randomized, double-blind, phase III trial consisting of two separate and fully independently powered study comparisons evaluating rucaparib monotherapy (ATHENA-MONO) and rucaparib in combination with nivolumab (ATHENA-COMBO) as maintenance treatment for patients with newly diagnosed advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer. ATHENA enrolled approximately 1000 patients across 24 countries, all women with newly diagnosed ovarian cancer who responded to their first-line chemotherapy. The trial completed accrual in 2020 and was conducted in association with the GOG Foundation, Inc. (GOG-F) in the U.S. and the European Network of Gynaecological Oncological Trial groups (ENGOT) in Europe. GOG-F and ENGOT are the two largest cooperative groups in the U.S. and Europe dedicated to the treatment of gynecological cancers.

ATHENA-MONO is evaluating the benefit of rucaparib monotherapy versus placebo in 538 women in this patient population. The primary efficacy analysis evaluated two prospectively defined molecular sub-groups in a step-down manner: 1) HRD-positive (inclusive of *BRCA* mutant) tumors, and 2) the intent-to-treat population, or all patients treated in ATHENA-MONO.

About the GOG Foundation, Inc. (www.gog.org)

The GOG Foundation, Inc. is a not-for-profit organization with the purpose of promoting excellence in the quality and integrity of clinical and translational scientific research in the field of gynecologic malignancies. The GOG Foundation is committed to maintaining the highest standards in clinical trials development, execution, analysis, and distribution of results. The GOG Foundation is the only clinical trialist group in the United States that focuses its research on patients with pelvic malignancies, such as cancer of the ovary (including surface peritoneal malignancies), uterus (including endometrium, soft tissue sarcoma, and gestational trophoblastic neoplasia), cervix, and vulva. The GOG Foundation is multi-disciplinary in its approach to clinical trials, and includes gynecologic oncologists, medical oncologists, pathologists, radiation oncologists, oncology nurses, biostatisticians (including those with expertise in bioinformatics), basic scientists, quality of life experts, data managers, and administrative personnel.

About the GOG Partners Program

Supported by industry, GOG Partners program is structured to work directly with pharmaceutical organizations and operate clinical trials outside the National Cancer Institute (NCI) framework. The GOG Partners program promotes the mission of the GOG Foundation dedicated to

transforming care in Gynecologic Oncology. By providing an alternative venue for patient accrual and site infrastructure support, GOG Partners has helped provide additional trials and opportunities for patients outside the national gynecologic clinical trials network.

About ENGOT (www.engot.esgo.org)

The European Network for Gynaecological Oncological Trial (ENGOT) groups is a research network of the European Society of Gynaecological Oncology (ESGO) and was founded in Berlin in October 2007. Currently, ENGOT consists of 21 trial groups from 33 European countries that perform cooperative clinical trials. ENGOT's ultimate goal is to bring the best treatment to gynaecological cancer patients through the best science and enabling every patient in every European country to access a clinical trial.

Rucaparib European Union (EU), including Northern Ireland, authorized use and Important Safety Information

Rucaparib is indicated as monotherapy for the maintenance treatment of adult patients with advanced (FIGO Stages III and IV) high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) following completion of first-line platinum-based chemotherapy.

Rucaparib is indicated as monotherapy for the maintenance treatment of adult patients with platinum-sensitive relapsed high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to platinum-based chemotherapy.

Efficacy of rucaparib as treatment for relapsed or progressive epithelial ovarian cancer (EOC), fallopian tube cancer (FTC), or primary peritoneal cancer (PPC) has not been investigated in patients who have received prior treatment with a PARP inhibitor. Therefore, use in this patient population is not recommended.

Summary warnings and precautions:

Hematological toxicity

During treatment with rucaparib, events of myelosuppression (anemia, neutropenia, thrombocytopenia) may be observed and are typically first observed after 8–10 weeks of treatment with rucaparib. These reactions are manageable with routine medical treatment and/or dose adjustment for more severe cases. Complete blood count testing prior to starting treatment with rucaparib and monthly thereafter is advised.

Patients should not start rucaparib treatment until they have recovered from hematological toxicities caused by previous chemotherapy (< CTCAE grade 1).

Supportive care and institutional guidelines should be implemented for the management of low blood counts for the treatment of anemia and neutropenia. Rucaparib should be interrupted, or

dose reduced according to Table 1 (see Posology and Method of Administration [4.2] of the Summary of Product Characteristics [SmPC]), and blood counts monitored weekly until recovery. If the levels have not recovered to CTCAE grade 1 or better after four weeks, the patient should be referred to a hematologist for further investigations.

MDS/AML

MDS/AML, including cases with fatal outcomes, have been reported in patients who received rucaparib. The duration of therapy with rucaparib in patients who developed MDS/AML varied from less than 2 months to approximately 6 years.

If MDS/AML is suspected, the patient should be referred to a hematologist for further investigations, including bone marrow analysis and blood sampling for cytogenetics. If, following investigation for prolonged hematological toxicity, MDS/AML is confirmed, rucaparib should be discontinued.

Photosensitivity

Photosensitivity has been observed in patients treated with rucaparib. Patients should avoid spending time in direct sunlight because they may burn more easily during rucaparib treatment; when outdoors, patients should wear a hat and protective clothing and use sunscreen and lip balm with sun protection factor of 50 or greater.

Gastrointestinal toxicities

Gastrointestinal toxicities (nausea and vomiting) are frequently reported with rucaparib and are generally low grade (CTCAE grade 1 or 2) and may be managed with dose reduction (refer to Posology and Method of Administration [4.2], Table 1 of the SmPC) or interruption. Antiemetics, such as 5-HT3 antagonists, dexamethasone, aprepitant, and fosaprepitant, can be used as treatment for nausea/vomiting and may also be considered for prophylactic (i.e., preventative) use prior to starting rucaparib. It is important to proactively manage these events to avoid prolonged or more severe events of nausea/vomiting, which have the potential to lead to complications such as dehydration or hospitalization.

Intestinal obstruction

Cases of intestinal obstruction have been observed in ovarian cancer patients treated with rucaparib in clinical trials; 3.5% of patients treated with rucaparib experienced a serious event of intestinal obstruction, with a fatal outcome in 1 rucaparib treated patient (less than 0.1%). The underlying disease may play a role in the development of intestinal obstruction in patients with ovarian cancer. In the event of suspected intestinal obstruction, a prompt diagnostic evaluation should be conducted, and the patient should be treated appropriately.

Embryofetal toxicity

Rucaparib can cause fetal harm when administered to a pregnant woman based on its mechanism of action and findings from animal studies. In an animal reproduction study, administration of rucaparib to pregnant rats during the period of organogenesis resulted in embryo-fetal toxicity at exposures below those in patients receiving the recommended human dose of 600 mg twice daily (see Preclinical Safety Data [5.3] of the SmPC).

Pregnancy/contraception

Pregnant women should be informed of the potential risk to a fetus. Women of reproductive potential should be advised to use effective contraception during treatment and for six months following the last dose of rucaparib (see section 4.6 of the SmPC). A pregnancy test before initiating treatment is recommended in women of reproductive potential.

Excipients

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say, essentially 'sodium-free.'

Click here to access the current EU SmPC (including for Northern Ireland).

Healthcare professionals should report any suspected adverse reactions via their national reporting systems.

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

Rucaparib Medicines and Healthcare products Regulatory Agency (MHRA) authorized use and Important Safety Information

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Efficacy of rucaparib as treatment for relapsed or progressive epithelial ovarian cancer (EOC), fallopian tube cancer (FTC), or primary peritoneal cancer (PPC) has not been investigated in patients who have received prior treatment with a PARP inhibitor. Therefore, use in this patient population is not recommended.

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Patients should not start rucaparib treatment until they have recovered from hematological toxicities caused by previous chemotherapy (≤ CTCAE grade 1).

Supportive care and institutional guidelines should be implemented for the management of low blood counts for the treatment of anemia and neutropenia. Rucaparib should be interrupted, or dose reduced according to Table 1 (see Posology and Method of Administration [4.2] of the Summary of Product Characteristics [SmPC]), and blood counts monitored weekly until recovery. If the levels have not recovered to CTCAE grade 1 or better after four weeks, the patient should be referred to a hematologist for further investigations.

Myelodysplastic syndrome (MDS)/acute myeloid leukemia (AML)

MDS/AML, including cases with fatal outcomes, have been reported in patients who received rucaparib. The duration of therapy with rucaparib in patients who developed MDS/AML varied from less than 2 months to approximately 6 years.

If MDS/AML is suspected, the patient should be referred to a hematologist for further investigations, including bone marrow analysis and blood sampling for cytogenetics. If, following investigation for prolonged hematological toxicity, MDS/AML is confirmed, rucaparib should be discontinued.

Photosensitivity

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Pregnancy/contraception

Pregnant women should be informed of the potential risk to a fetus. Women of reproductive potential should be advised to use effective contraception during treatment and for six months following the last dose of rucaparib (see section 4.6 of the SmPC). A pregnancy test before initiating treatment is recommended in women of reproductive potential.

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Click here to access the current MHRA SmPC.

Healthcare professionals should report any suspected adverse reactions via their national reporting systems.

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

Rucaparib Ovarian Cancer U.S. FDA-Approved Indication

Rucaparib is indicated for the maintenance treatment of adult patients with a deleterious *BRCA* mutation (germline and/or somatic)-associated recurrent epithelial ovarian, fallopian tube, or

primary peritoneal cancer, who are in a complete or partial response to platinum-based chemotherapy.

Select Important Safety Information

Myelodysplastic Syndrome (MDS)/Acute Myeloid Leukemia (AML) occur in patients treated with rucaparib, and are potentially fatal adverse reactions. In 2141 treated patients with ovarian and prostate cancer [see Adverse Reactions (6.1)], MDS/AML occurred in 34 patients (1.6%), including those in long term follow-up. Of these, 14 occurred during treatment or during the 28-day safety follow-up (0.7%). The duration of RUBRACA treatment prior to the diagnosis of MDS/AML ranged from < 2 months to approximately 72 months. The cases were typical of secondary MDS/cancer therapy-related AML; in all cases, patients had received previous platinum-containing chemotherapy regimens and/or other DNA damaging agents.

In ARIEL3, of patients with a germline and/or somatic *BRCA* mutation treated with rucaparib, MDS/AML occurred in 9 out of 129 (7%) patients treated with rucaparib and 4 out of 66 (6%) patients treated with placebo. The duration of therapy with rucaparib in patients who developed secondary MDS/cancer therapy-related AML varied from 1.2 to 4.7 years.

Do not start rucaparib 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 rucaparib 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 rucaparib.

Based on its mechanism of action and findings from animal studies, rucaparib 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 rucaparib.

Most common adverse reactions in patients with *BRCA*-mutated ovarian cancer in ARIEL3 (≥ 20%; Grade 1-4) were nausea (79%), fatigue/asthenia (74%), abdominal pain/distention (48%), rash (45%), anemia (41%), constipation (39%), vomiting (37%), thrombocytopenia (35%), diarrhea (34%), dysgeusia (33%), AST/ALT elevation (33%), nasopharyngitis/upper respiratory tract infection (29%), stomatitis (28%), decreased appetite (23%), and neutropenia (22%).

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 rucaparib, advise lactating women not to breastfeed during treatment with rucaparib and for 2 weeks after the last dose.

Please click here for full Prescribing Information for rucaparib.

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.

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

About pharma& (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. Since its inception, pharma& has acquired and integrated 10+ high-need specialty therapeutics, expanding its portfolio across a wide range of therapy areas, with an increasing focus on hematology and oncology treatments. pharma& provides its portfolio of medicines to eligible patients worldwide by spanning the continuum of research and development, in-house product and active pharmaceutical ingredient (API) manufacturing, distribution via its global partner network, healthcare provider engagement, patient safety services, and patient access services.

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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.

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pharma& Media Contact:
media@pharmaand.com

References

1. Zagouri F, Diaz JP, Zeng X, et al. Rucaparib Maintenance in ATHENA-MONO (GOG-3020/ENGOT-ov45) in Patients with Newly Diagnosed Advanced Ovarian Cancer: Exploratory Post-Progression Evaluations for Patients with HRD-Negative and HRD-Unknown Tumors. Presented at ESGO's 27th European Gynaecological Oncology Congress 2026, 27 February, Copenhagen, Denmark.

2. Kristeleit RS, Ghamande S, Lisyanskaya A, et al. Rucaparib Maintenance for Newly Diagnosed Advanced Ovarian Cancer: Interim Overall Survival, Progression-free Survival, and Safety at 5 Years of Follow-up From the Phase III ATHENA-MONO/GOG-3020/ENGOT-ov45 Study. Ann Oncol. 2026;37:217-228.

3. Monk BJ, Parkinson C, Lim MC, et al. A Randomized, Phase III Trial to Evaluate Rucaparib Monotherapy as Maintenance Treatment in Patients with Newly Diagnosed Ovarian Cancer (ATHENA-MONO/GOG-3020/ENGOT-ov45). J Clin Oncol. 2022;40:3952-3964.