pharma&'s Rubraca® (rucaparib) ATHENA-MONO Clinical Trial Data in First-Line Maintenance Treatment Suggest Benefit Continues Beyond Completion of Treatment and First Progression

Intended for the Media

Vienna, Austria, March 16, 2024 – pharmaand GmbH (pharma&) announced today the presentation of data from the randomized, Phase 3 Company-sponsored ATHENA (GOG-3020/ENGOT-ov45) trial (ATHENA-MONO) monotherapy versus placebo presented on Saturday, March 16, 2024, during the Society of Gynecologic Oncology (SGO) Annual Meeting held in San Diego, California, U.S.A. Dr. Rebecca S. Kristeleit MD, PhD, of Guy's and St Thomas' NHS Foundation Trust in London and lead ENGOT/NCRI National Cancer Research Institute (https://www.ncri.org.uk/) investigator of the ATHENA trial will present the oral presentation, "Interim Post-Progression Data and Updated Survival in Patients with Newly Diagnosed Advanced Ovarian Cancer in ATHENA-MONO."

The ATHENA-MONO trial data demonstrate that rucaparib, as a first-line maintenance treatment with three years of follow-up, time to first subsequent therapy (TFST), and progression-free survival 2 (PFS2) interim data suggest that rucaparib benefit continues beyond completion of treatment and first progression.[1,2] Analyses of TFST and PFS2 suggested there was a greater clinical benefit with rucaparib versus placebo for the homologous recombination deficiency (HRD) and intent to treat (ITT) populations. The second interim analysis of overall survival (OS) showed a hazard ratio of <1 in the HRD (25% maturity) and ITT (35% maturity) populations. The estimated median OS was not reached at the time of data cutoff, except for the placebo arm of the ITT group.

"This interim post-progression data and updated survival from the ATHENA-MONO portion of the trial continue to validate the use of rucaparib for the first-line

[1] time to first subsequent therapy (TFST) – defined as the time from initiation of first-line chemotherapy until the start of subsequent therapy or death.
[2] progression-free survival 2 (PFS2) - defined as the time from initial study randomization to second disease progression or death from any cause.

maintenance treatment of advanced ovarian cancer in the homologous recombination deficiency (HRD) and intent to treat (ITT) populations," said Rebecca S. Kristeleit, MD, PhD, of Guy's and St Thomas' NHS Foundation Trust in London and lead ENGOT/NCRI National Cancer Research Institute (https://www.ncri.org.uk/) investigator of the ATHENA trial. "Rucaparib reduced the risk of disease progression in patients compared to placebo as measured by the time to first subsequent therapy, progression-free survival 2, and overall survival hazard ratios across both the homologous recombination deficiency (HRD) and intent to treat (ITT) populations."

The 3-year follow-up interim TFST, PFS2, and OS outcomes presented are from ATHENA-MONO using a data cutoff of March 9, 2023. This long-term data, in addition to the primary endpoint analysis and safety data using a data cutoff of March 23, 2022, was taken to support the first-line maintenance approval of rucaparib by the European Medicines Agency (EMA) (15 Nov 2023) and the Medicines and Healthcare products Regulatory Agency (MHRH) (15 Jan 2024). Rucaparib is not currently FDA-approved in the first-line ovarian cancer maintenance setting.

Interim TFST Results in the Primary Analysis HRD and ITT Populations

For the endpoint of interim TFST in the HRD-positive (tBRCA + non-tBRCA LOH^{high}) patient population, the rucaparib arm (n=185) showed a delay in the time between randomization and the first subsequent treatment over the placebo arm (n=49) with a hazard ratio of 0.50 (95% CI: 0.33-0.76). The median TFST for the HRD-positive patient population treated with rucaparib was 32.7 months compared to 15.1 months among those who received placebo.

For the endpoint of interim TFST in the ITT patient population, the rucaparib arm (n=427) showed a delay in the time between randomization and the first subsequent treatment over the placebo arm (n=111) with a hazard ratio of 0.52 (95% CI: 0.40-0.67). The median TFST for the ITT patient population treated with rucaparib was 23.3 months compared to 12.1 months among those who received placebo.

Interim PFS2 Results in the Primary Analysis HRD and ITT Populations

For the endpoint of interim PFS2 in the HRD-positive (tBRCA + non-tBRCA LOH^{high}) patient population, the rucaparib arm (n=185) showed improvement over the placebo arm (n=49) with a hazard ratio of 0.75 (95% CI: 0.46-1.24), representing a 25% reduction in the

risk of disease progression. The median PFS2 for the HRD-positive patient population treated with rucaparib was not reached compared to 39.9 months among those who received placebo.

For the endpoint of interim PFS2 in the ITT patient population, the rucaparib arm (n=427) showed improvement over the placebo arm (n=111) with a hazard ratio of 0.84 (95% CI: 0.63-1.13), representing a 16% reduction in the risk of disease progression. The median PFS2 for the ITT patient population treated with rucaparib was 36 months compared to 26.8 months among those who received placebo.

Interim OS Results in the Primary Analysis HRD and ITT Populations

With the additional follow-up of approximately one year since the interim analysis performed at the time of the primary endpoint analysis, the hazard ratio decreased numerically in the HRD-positive (tBRCA + non-tBRCA LOH^{high}) patient population (25% maturity, HR 0.84 [95% CI: 0.44-1.58]) and the ITT patient population (35% maturity, HR 0.83 [95% CI: 0.58-1.17]). Median OS was not reached at the time of data cutoff, except for the placebo arm of the ITT group, which was 46.2 months. The median OS was not reached in the HRD-positive population treated with rucaparib or those who received placebo arms. The estimated 12 and 24-month OS rates of Rubraca in the HRD and ITT populations showed a hazard ratio of 0.95 (0.91-0.97) and 0.85 (0.78-0.89) and 0.93 (0.90-0.96) and 0.77 (0.66-0.83), respectively.

Treatment Benefit in Exploratory Subgroups

tBRCA-mutant Subgroup:

For TFST, the rucaparib arm (n=91) demonstrated benefit over the placebo arm (n=24), with a hazard ratio of 0.52 (95% CI: 0.28-0.96), representing a delay from the time of randomization to the start of subsequent treatment. The median TFST was not reached for those treated with rucaparib compared to 25.7 months for those who received placebo.

For PFS2, the rucaparib arm (n=91) demonstrated benefit over the placebo arm (n=24), with a hazard ratio of 0.73 (95% CI: 0.34-1.54), representing a 27% reduction in the risk of disease progression. The median PFS2 was not reached for those treated with rucaparib or for those who received placebo.

For the endpoint interim OS, the rucaparib arm (n=91) demonstrated over the placebo arm (n=24) a hazard ratio of 1.51 (95% CI: 0.47-4.86). The median OS was not reached for those treated with rucaparib or for those who received placebo. The maturity of OS in this small tBRCA-mutant subgroup is the most immature compared to other HRD subgroups.

Non-tBRCA LOH^{high} Subgroup:

For TFST, the rucaparib arm (n=94) demonstrated benefit over the placebo arm (n=25), with a hazard ratio of 0.55 (95% CI: 0.33-0.95), representing a delay from the time of randomization to the start of subsequent treatment. The median TFST was 26.1 months for those treated with rucaparib compared to 12.0 months for those who received placebo.

For PFS2, the rucaparib arm (n=94) demonstrated benefit over the placebo arm (n=25), with a hazard ratio of 0.83 (95% CI: 0.43-1.30), representing a 17% reduction in the risk of disease progression. The median PFS2 was 39.0 months for those treated with rucaparib and was not reached for those who received placebo.

For the endpoint interim OS, the rucaparib arm (n=94) demonstrated benefit over the placebo arm (n=25), with a hazard ratio of 0.61 (95% CI: 0.29-1.30). The median OS was not reached for those treated with rucaparib compared to 41.0 months for those who received placebo.

Non-tBRCA LOH^{low} Subgroup:

For TFST, the rucaparib arm (n=189) demonstrated benefit over the placebo arm (n=49), with a hazard ratio of 0.56 (95% CI: 0.40-0.80), representing a delay from the time of randomization to the start of the subsequent treatment. The median TFST was 16.2 months for those treated with rucaparib compared to 10.4 months for those who received placebo.

For PFS2, the rucaparib arm (n=189) demonstrated benefit over the placebo arm (n=49), with a hazard ratio of 0.77 (95% CI: 0.52-1.14), representing a 23% reduction in the risk of disease progression. The median PFS2 was 24.4 months for those treated with rucaparib and 20.0 months for those who received placebo.

For the endpoint interim OS, the rucaparib arm (n=189) demonstrated benefit over the placebo arm (n=49), with a hazard ratio of 0.75 (95% CI: 0.48-1.17). The median OS was 42.9 months for those treated with rucaparib compared to 32.4 months for those who received placebo.

Non-tBRCA LOH^{unknown} Subgroup:

For TFST, the rucaparib arm (n=53) demonstrated benefit over the placebo arm (n=13), with a hazard ratio of 0.45 (95% CI: 0.23-0.88), representing a delay from the time of randomization to the start of subsequent treatment. The median TFST was 19.4 months for those treated with rucaparib compared to 12.0 months for those who received placebo.

For PFS2, the rucaparib arm (n=53) demonstrated over the placebo arm (n=13) a hazard ratio of 1.05 (95% CI: 0.44-2.50), representing a detrimental risk of disease progression. The median PFS2 was 29.0 months for those treated with rucaparib and was not reached for those who received placebo.

For the endpoint interim OS, the rucaparib arm (n=53) demonstrated benefit over the placebo arm (n=13), with a hazard ratio of 1.08 (95% CI: 0.38-3.09). The median OS was not reached for those treated with rucaparib or for those who received placebo.

"These results further confirm that eligible patients with advanced ovarian cancer can benefit from first-line maintenance treatment with Rubraca," said Frank Rotmann, Founder and Managing Director, pharma&. "We continue to thank all patients, caregivers, and physicians who participated in this trial, the results of which we believe further demonstrate the potential benefit Rubraca can offer to eligible women with advanced ovarian cancer in the first-line maintenance treatment setting."

Rubraca Ovarian Cancer U.S. FDA Approved Indication

Rubraca 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 Rubraca, and are potentially fatal adverse reactions. In 1594 treated patients with ovarian cancer [see Adverse Reactions (6.1)], MDS/AML occurred in 32 patients (2%), including those in long term follow-up. Of these, 14 occurred during treatment or during the 28-day safety follow-up (0.9%). 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.

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.

Most common adverse reactions in ARIEL3 (≥ 20%; Grade 1-4) were nausea (76%), fatigue/asthenia (73%), abdominal pain/distention (46%), rash (43%), dysgeusia (40%), anemia (39%), AST/ALT elevation (38%), constipation (37%), vomiting (37%), diarrhea (32%), thrombocytopenia (29%), nasopharyngitis/upper respiratory tract infection (29%), stomatitis (28%), decreased appetite (23%), and neutropenia (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.

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.

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

Rubraca 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 [SPC]), 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 SPC).

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 SPC). 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.

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

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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 Rubraca monotherapy (ATHENA-MONO) and Rubraca 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 Gynecologic Oncology Group (GOG) in the US and the European Network of Gynaecological Oncological Trial groups (ENGOT) in Europe. GOG and ENGOT are the two largest cooperative groups in the US and Europe dedicated to the treatment of gynecological cancers.

ATHENA-MONO is evaluating the benefit of Rubraca 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.

The ATHENA-COMBO portion of the trial, is evaluating the magnitude of benefit of adding Opdivo (nivolumab) to Rubraca monotherapy in the ovarian cancer first-line maintenance treatment setting.

About Ovarian Cancer

Ovarian cancer is the eighth leading cause of cancer-related death among women worldwide. In 2020, GLOBOCAN estimated 314,000 women received a new diagnosis of ovarian cancer and approximately 207,200 women died from ovarian cancer. According to the American Cancer Society, an estimated more than 19,000 women will be diagnosed with ovarian cancer in the United States and there will be an estimated nearly 13,000 deaths from ovarian cancer in 2023. According to GLOBOCAN, an estimated 66,000 women in Europe are diagnosed each year with ovarian cancer, and ovarian cancer is among those cancers with the highest rate of deaths. According to the NIH National Cancer Institute, more than 75% of women are diagnosed with ovarian cancer at an advanced stage.

Despite recent advances in the therapeutic landscape of newly diagnosed ovarian cancer, advanced ovarian cancer is still considered incurable for the majority of patients, and the optimal treatment strategy has yet to be determined.[i] Although most respond initially to this treatment, 80% of patients with advanced ovarian cancer will have a recurrence and require subsequent therapies.[ii]

About pharma&

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& holds the worldwide rights for Rubraca®.

To the extent that statements contained in this press release are not descriptions of historical facts regarding pharma&, they are forward-looking statements reflecting the current beliefs and expectations of management. Examples of forward-looking statements contained in this press release include, among others, statements of our intentions and expectations for our development programs, including potential indications, tumor types, plans for presentation of data with respect to Rubraca. Such forward-looking statements involve substantial risks and uncertainties that could cause pharma&'s actual results, performance, or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the uncertainties inherent in clinical development, including the outcome of clinical trials, whether initial results, findings, or research will support future studies or development, whether future study results will be consistent with previous study findings or other results, results in named-patient or similar programs or clinical trials, whether additional studies not originally contemplated are determined to be necessary, the timing of initiation, enrollment and completion of planned studies and actions by regulatory authorities regarding data required to support drug applications and whether to approve drug applications. pharma& undertakes no obligation to update or revise any forward-looking statements.

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media@pharmaand.com

[i] Monk BJ et al. ATHENA (GOG-3020/ENGOT-ov45): a randomized, phase III trial to evaluate rucaparib as monotherapy (ATHENA–MONO) and rucaparib in combination with nivolumab (ATHENA–COMBO) as maintenance treatment following frontline platinum-based chemotherapy in ovarian cancer. Int J Gynecol Cancer. 2021;0:1–6.

[ii] Hanker LC et al. The impact of second to sixth line therapy on survival of relapsed ovarian cancer after primary taxane/platinum-based therapy. Ann Oncol. 2012;23(10):2605-2612. doi:10.1093/annonc/mds203.