pharma& Announces Rubraca® (rucaparib) Global Success and Expansion Q1 2025 Update

- *A license and supply agreement with Hikma Pharmaceuticals will expand rucaparib distribution throughout the Middle East and North Africa (MENA)*
- *Rucaparib is now reimbursed in both Sweden and Poland as a first-line maintenance treatment for eligible women with advanced ovarian cancer*

Intended for the Healthcare Media

Vienna, Austria, April 10, 2025 – pharmaand GmbH (pharma&) announced today Q1 2025 Rubraca® (rucaparib) expansion and reimbursement updates, including expanded access to rucaparib in the Middle East and North Africa (MENA) through a License and Supply Agreement with Hikma Pharmaceuticals (Hikma), and the reimbursement of rucaparib in Sweden and Poland as a first-line maintenance treatment for eligible women with advanced ovarian cancer.

"Recent reimbursement decisions in Sweden and Poland and the agreement with Hikma to expand access into the Middle East and North Africa represent significant advancements as pharma& continues to expand global availability to rucaparib," said Elmar Zagler, Co-Founder and Managing Director of pharma&. "These developments mean a greater number of eligible patients in additional regions worldwide could benefit from rucaparib treatment."

Agreement with Hikma Brings Rucaparib Access to the Middle East and North Africa

pharma& has entered a License and Supply Agreement whereby Hikma will commercialize rucaparib into the Middle East and North Africa (MENA). Effective March 27, 2025, Hikma has exclusive rights to commercialize rucaparib in MENA countries, including Algeria, Bahrain, Egypt, Iraq including Kurdistan, Jordan, Kuwait, Lebanon, Libya, Morocco, Oman, Palestine, Saudi Arabia, Syria, Sudan, Tunisia, United Arab Emirates, and Yemen.

Hikma, headquartered in the United Kingdom (UK), is a global company with a local presence across North America, the Middle East and North Africa (MENA) and Europe. It uses its unique insight and expertise to transform cutting-edge science into innovative solutions that transform people's lives. It is a leading licensing partner, and through its venture capital arm, it is helping bring innovative health technologies to people worldwide. For more information, please visit www.hikma.com.

First-Line Maintenance Treatment Rucaparib Reimbursement in Sweden and Poland

Rucaparib has received reimbursement approval in Sweden, effective February 1, 2025, as a monotherapy for the maintenance treatment of women with advanced (FIGO Stages III and IV)

high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) who have achieved a complete or partial response following first-line platinum-based chemotherapy.

pharma&'s Nordics business partner, GHN Pharma, is commercializing Rubraca in Sweden.

Rucaparib has also received reimbursement approval in Poland, effective from April 1, 2025, as a monotherapy for the maintenance treatment of patients with advanced (FIGO Stages III and IV) ovarian, fallopian tube, or primary peritoneal cancer who have achieved a complete or partial response following first-line platinum-based chemotherapy.

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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 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 death. 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]

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

Rubraca® (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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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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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& holds the worldwide rights for Rubraca®.

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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References

[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.