



NEWS RELEASE

Clovis Oncology Announces Oral Plenary Session Presentation at International Gynecologic Cancer Society (IGCS) Digital Annual Global Meeting

9/10/2020

Accepted abstract describes exploratory analysis from ARIEL3 further suggesting the durable clinical benefit of Rubraca maintenance treatment beyond progression for women with platinum-sensitive recurrent ovarian cancer with BRCA1/2 mutations

BOULDER, Colo.--(BUSINESS WIRE)-- Clovis Oncology, Inc. (NASDAQ: CLVS), announced today that an abstract featuring data from an exploratory analysis of the ARIEL3 clinical study evaluating Rubraca® (rucaparib) as maintenance treatment in recurrent ovarian cancer has been accepted for presentation in an oral plenary session at the International Gynecologic Cancer Society (IGCS) Digital Annual Global Meeting taking place September 10–13. The findings of the analysis demonstrate that rucaparib maintenance treatment can lead to a clinically meaningful delay in starting subsequent therapy and lasting clinical benefits in patients with BRCA1- or BRCA2-mutant ovarian cancer.

“This exploratory analysis examining the subgroup of patients with advanced recurrent ovarian cancer and a BRCA1 or BRCA2 mutation suggest the durability of the clinical benefit of rucaparib maintenance,” said Johanne Weberpals M.D., Gynecologic Oncologist, Ottawa Hospital Research Institute. “These data reinforce the potential benefit of rucaparib in this patient population.”

“Together with ARIEL3 results we have previously published and presented, these data highlight the clinical benefit that Rubraca offers as a maintenance therapy for patients with recurrent ovarian cancer,” said Patrick J. Mahaffy, President and CEO of Clovis Oncology. “We look forward to sharing these data with the research and medical community at this year’s digital IGCS global meeting and continuing the important dialogue around the benefits of Rubraca for the treatment of advanced ovarian cancer.”

Following are details regarding the Rubraca abstract to be presented today at IGCS:

Abstract Number: IGCS20_1268- Postprogression Efficacy Outcomes from the Phase 3 ARIEL3 Study of Rucaparib in Patients With Platinum-Sensitive Recurrent Ovarian Carcinoma Associated With Either BRCA1 or BRCA2 Mutations

- Presenting Author: Johanne I. Weberpals, MD
- Session: Plenary I

The presentation will take place during the Plenary I session which will be broadcast on Thursday, September 10, 2020 from 14:00-15:00 UTC; the specific presentation time is 14:47-14:54 UTC. In addition, the presentation will be available at <https://www.clovisoncology.com/pipeline/scientific-presentations/> following the Plenary I session.

About Rubraca (rucaparib)

Rucaparib is an oral, small molecule inhibitor of PARP1, PARP2 and PARP3 being developed in multiple tumor types, including ovarian and metastatic castration-resistant prostate cancers, as monotherapy, and in combination with other anti-cancer agents. Exploratory studies in other tumor types are also underway.

Rubraca is an unlicensed medical product outside of the U.S. and Europe.

Rubraca® (rucaparib) European Union (EU) authorized use and Important Safety Information

Rubraca 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.

Rubraca is indicated as monotherapy treatment of adult patients with platinum sensitive, relapsed or progressive, BRCA mutated (germline and/or somatic), high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have been treated with ≥ 2 prior lines of platinum-based chemotherapy, and who are unable to tolerate further platinum-based chemotherapy.

Efficacy of Rubraca as treatment for relapsed or progressive EOC, FTC, or 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 Rubraca, events of myelosuppression (anemia, neutropenia, thrombocytopenia) may be observed and are typically first observed after 8–10 weeks of treatment with Rubraca. 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 Rubraca, and monthly thereafter, is advised. Patients should not start Rubraca 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. Rubraca 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 4 weeks, the patient should be referred to a hematologist for further investigations.

MDS/AML

MDS/AML, including cases with fatal outcome, have been reported in patients who received Rubraca. The duration of therapy with Rubraca in patients who developed MDS/AML varied from less than 1 month to approximately 28 months.

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, Rubraca should be discontinued.

Photosensitivity

Photosensitivity has been observed in patients treated with Rubraca. Patients should avoid spending time in direct sunlight because they may burn more easily during Rubraca 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 Rubraca, 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 SPC) 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 Rubraca. 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.

Embryofetal toxicity

Rubraca 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 Rubraca 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 6 months following the last dose of Rubraca (see section 4.6 of the SPC). A pregnancy test before initiating treatment is recommended in women of reproductive potential.

Click here to access the current SPC. Healthcare professionals should report any suspected adverse reactions via their national reporting systems.

Rubraca U.S. FDA Approved Indications

Ovarian Cancer

Rubraca is indicated for the maintenance treatment of adult women with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy.

Rubraca is indicated for the treatment of adult women with a deleterious BRCA mutation (germline and/or somatic)-associated epithelial ovarian, fallopian tube, or primary peritoneal cancer who have been treated with two or more chemotherapies. Select patients for therapy based on an FDA-approved companion diagnostic for Rubraca.

Prostate Cancer

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) occur in patients treated with Rubraca, and are potentially fatal adverse reactions. In 1146 treated patients, MDS/AML occurred in 20 patients (1.7%), including those in long term follow-up. Of these, 8 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 1 month to approximately 53 months. The cases were typical of secondary MDS/cancer therapy-related AML; in all cases, patients had received previous platinum-containing regimens and/or other DNA damaging agents.

Do not start Rubraca until patients have recovered from hematological toxicity caused by previous chemotherapy (\leq 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. Advise 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.

Most common adverse reactions in ARIEL3 (\geq 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%).

Most common adverse reactions in Study 10 and ARIEL2 (\geq 20%; Grade 1-4) were nausea (77%), asthenia/fatigue (77%), vomiting (46%), anemia (44%), constipation (40%), dysgeusia (39%), decreased appetite (39%), diarrhea (34%), abdominal pain (32%), dyspnea (21%), and thrombocytopenia (21%).

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.

About Clovis Oncology

Clovis Oncology, Inc. is a biopharmaceutical company focused on acquiring, developing and commercializing innovative anti-cancer agents in the U.S., Europe and additional international markets. Clovis Oncology targets development programs at specific subsets of cancer populations, and simultaneously develops, with partners, diagnostic tools intended to direct a compound in development to the population that is most likely to benefit from its use. Clovis Oncology is headquartered in Boulder, Colorado; please visit www.clovisoncology.com for more information, including additional office locations in the U.S. and Europe.

To the extent that statements contained in this press release are not descriptions of historical facts regarding Clovis Oncology, 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 regarding our expectations for submission of regulatory filings, the timing and pace of commencement of and enrollment in our clinical trials, including those being planned or conducted in collaboration with partners, the potential results of such clinical trials, our expectations regarding the suitability of Rubraca for, and our plans to develop Rubraca in, additional indications and tumor types. Such forward-looking statements involve substantial risks and uncertainties that could cause our future results, performance or achievements to differ significantly from that expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the uncertainties inherent in our clinical development programs for our drug candidates and those of our partners, whether future study results will be consistent with study findings to date, the timing of availability of data from our clinical trials and the initiation, enrollment, timing and results of our planned clinical trials and the corresponding development pathways, effectiveness and suitability of diagnostic tests, the risk that final results of ongoing trials may differ from initial or interim results as a result of factors such as final results from a larger patient population may be different from initial or interim results from a smaller patient population, the risk that additional pre-clinical or clinical studies may not support further development in certain additional indications or tumor types, and actions by the FDA, the EMA or other regulatory authorities regarding data required to support drug applications and whether to approve drug applications. Clovis Oncology does not undertake to update or revise any forward-looking statements. A further description of risks and uncertainties can be found in Clovis Oncology's filings with the Securities and Exchange Commission, including its Annual Report on Form 10-K and its reports on Form 10-Q and Form 8-K.

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