NEWS RELEASE

Clovis Oncology to Highlight Rubraca® (rucaparib) Data from Post-Hoc ARIEL3 Analyses at SGO 2019 Congress

3/16/2019

- Exploratory analyses of ARIEL3 Rubraca data in recurrent ovarian cancer presented in oral plenary and poster sessions
- Maintenance treatment with Rubraca improved median progression-free survival (PFS) and reduced the risk of progression vs placebo regardless of age subgroup
- Maintenance treatment with Rubraca significantly improved PFS and reduced the risk of progression vs placebo regardless of whether tumors had deleterious germline BRCA mutations
- Safety profile of Rubraca was consistent with the overall safety population previously reported

BOULDER, Colo.--(BUSINESS WIRE)-- Clovis Oncology, Inc. (NASDAQ: CLVS) today announced that data from post hoc exploratory analyses from the ARIEL3 Phase 3 clinical study of Rubraca will be presented during oral plenary and poster sessions at the Society of Gynecologic Oncology 2019 Congress (SGO), March 16 -19, 2019 in Honolulu, Hawaii. Data to be presented will highlight ARIEL3 results in different patient demographics, including age and deleterious germline mutation status.

“The results from these post hoc analyses of the ARIEL3 study data underscore the safety and efficacy of Rubraca across a broad range of women with recurrent ovarian cancer,” said Patrick J. Mahaffy, President and CEO of Clovis Oncology. “We hope that our continuing exploration, analysis and publication of ARIEL3 data will help inform treatment decisions as well as the management of advanced ovarian cancer.”

Included in the SGO 2019 Congress Scientific Plenary 1 session is the following:

Title: The effect of age on efficacy and safety outcomes with rucaparib: a post hoc exploratory analysis of ARIEL3, a phase 3, randomized, placebo-controlled maintenance study in patients with recurrent ovarian carcinoma

Presenter: Jonathan A. Ledermann

Session: Scientific Plenary I: Snap, Crackle, PARP

Date/Time: March 16, 2019; 6:45 – 7:45am (HST) // 12:45 – 11:45pm (EDT)

Location: Kamehameha 3

Summary: The efficacy and safety of Rubraca maintenance treatment was investigated in three age-based sub-groups from ARIEL3 in a post-hoc exploratory analysis. In the intent-to-treat (ITT) population, investigator-assessed median PFS for patients aged <65 years was 11.1 months (n=237) in the Rubraca arm vs 5.4 months (n=117) in the placebo arm (hazard ratio [HR], 0.33; 95% confidence interval [CI], 0.25–0.43); for patients aged 65–74 years, median PFS was 8.3 months (n=113) vs 5.3 months (n=64) (HR, 0.43; 95% CI, 0.29–0.64); and for patients aged ≥75 years, median PFS was 9.2 months (n=25) vs 5.5 months (n=8) (HR, 0.47; 95% CI, 0.16–1.35).

In this dataset, maintenance treatment with Rubraca improved median PFS and reduced the risk of progression vs placebo regardless of age subgroup. In general, the safety profile of Rubraca was consistent across the three age subgroups.

“As we continue to explore and expand our use of PARP inhibitors for the maintenance treatment of recurrent ovarian cancer, it’s helpful for physicians to know how individual factors such as patient age may impact treatment decisions,” said Professor Jonathan Ledermann, MD, Professor of Medical Oncology, UCL Cancer Institute and UCL Hospitals, London, Global Principal Investigator for non-US sites in the ARIEL3 study. “In our analysis of the ARIEL3 study, we found that maintenance treatment with Rubraca improved median PFS, reduced the risk of progression and had a consistent safety profile regardless of age, suggesting that patient age should not discourage physicians from considering Rubraca in this setting.”

Included in an SGO 2019 Congress poster presentation session is the following:

Title: Post hoc exploratory analysis of rucaparib in patients with platinum-sensitive recurrent ovarian carcinoma from the randomized, placebo-controlled phase 3 study ARIEL3: effect of a deleterious germline or no germline BRCA mutation on efficacy and safety

Presenter: Robert L. Coleman

Date/Time: March 18, 2019; 6:00 – 10:00am and 3:30 – 5:00pm (HST)// 12:00 – 4:00pm and 9:30 –11pm (EDT)

Location: Kamehameha 2

Summary: For this analysis, researchers assessed PFS in the subgroup of patients with a deleterious germline BRCA mutation (germline BRCA mutation) and in patients without a deleterious germline BRCA mutation (no germline BRCA mutation). In these subgroups, Rubraca significantly improved PFS vs placebo regardless of BRCA mutation status. Although the reduction in risk was numerically greater in the germline BRCA mutation subgroup (hazard ratio [HR], 0.25; 95% confidence interval [CI], 0.16–0.39) than in the no germline BRCA mutation subgroup (HR, 0.41; 95% CI, 0.32–0.52), the reduction in risk between the two subgroups did not differ by a statistically significant margin. The safety profile of Rubraca vs placebo in the germline BRCA mutation and no germline BRCA mutation subgroups was consistent with the safety profile of Rubraca in the overall safety population reported previously.

This post hoc exploratory analysis demonstrated that the reduction in risk was numerically greater in the germline BRCA mutation subgroup than in the no germline BRCA mutation subgroup. In the no germline BRCA mutation subgroup, the observed improvement in PFS was not driven solely by the somatic BRCA mutation + wild-type BRCA/high LOH subgroup as demonstrated by the analysis of patients with wild-type BRCA tumors.

“While it is evident that women whose tumors possess a BRCA mutation derive the greatest benefit from rucaparib therapy, the data presented in this poster demonstrate the meaningful and clinically relevant benefit that eligible patients, including those without a BRCA mutation, may receive as a result of maintenance treatment,” said Robert L. Coleman, MD, Professor, Gynecologic Oncology and Reproductive Medicine at The University of Texas MD Anderson Cancer Center in Houston and co-Coordinating Investigator in the ARIEL3 clinical trial program. “These data further reinforce the importance of maintenance treatment for women with recurrent ovarian cancer versus the previous standard of observation following treatment with chemotherapy.”

About the ARIEL3 Clinical Trial

The ARIEL3 pivotal study of rucaparib is a confirmatory randomized, double-blind study comparing the effects of rucaparib against placebo to evaluate whether rucaparib given as a maintenance treatment to platinum-sensitive ovarian cancer patients can extend the period of time for which the disease is controlled after a complete or partial response to platinum-based chemotherapy. The study enrolled 564 patients with high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer. To be eligible for the study, participants had to have received at least two prior platinum-based treatment regimens, been sensitive to the penultimate platinum regimen, and achieved a complete or partial response to their most recent platinum-based regimen. There were no genomic selection criteria for this study. Trial participants were randomized 2:1 to receive 600 milligrams of rucaparib twice daily (BID) or placebo. The study achieved its primary endpoint of improved PFS by investigator review in each of three populations. PFS was also improved in the rucaparib group compared with placebo by independent review, a key secondary endpoint, in all three populations. In addition, rucaparib improved objective response rate vs placebo

among evaluable trial participants in all three study populations.

About Rubraca ® (rucaparib)

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

Clovis holds worldwide rights for Rubraca. Rubraca is an unlicensed medical product outside of the U.S. and the EU.

Rubraca U.S. FDA Approved Indications and Important Safety Information

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

Select Important Safety Information

Myelodysplastic Syndrome (MDS)/Acute Myeloid Leukemia (AML) occur uncommonly in patients treated with Rubraca, and are potentially fatal adverse reactions. In approximately 1100 treated patients, MDS/AML occurred in 12 patients (1.1%), including those in long-term follow-up. Of these, five occurred during treatment or during the 28-day safety follow-up (0.5%). The duration of Rubraca treatment prior to the diagnosis of MDS/AML ranged from 1 month to approximately 28 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 (≤ 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 (see Dosage and Administration [2.2] in full Prescribing Information) 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 cytogenetic analysis. 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%).

Most common laboratory abnormalities in ARIEL3 (≥ 25%; Grade 1–4) were increase in creatinine (98%), decrease in hemoglobin (88%), increase in cholesterol (84%), increase in alanine aminotransferase (ALT) (73%), increase in aspartate aminotransferase (AST) (61%), decrease in platelets (44%), decrease in leukocytes (44%), decrease in neutrophils (38%), increase in alkaline phosphatase (37%) and decrease in lymphocytes (29%).

Most common adverse reactions in Study 10 and ARIEL2 (≥ 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%).

Most common laboratory abnormalities in Study 10 and ARIEL2 (≥ 35%; Grade 1–4) were increase in creatinine (92%), increase in alanine aminotransferase (ALT) (74%), increase in aspartate aminotransferase (AST) (73%), decrease in hemoglobin (67%), decrease in lymphocytes (45%), increase in cholesterol (40%), decrease in platelets (39%) and decrease in absolute neutrophil count (35%).

Co-administration of Rubraca 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. You may report side effects to the FDA at 1-800-FDA-1088 or **www.fda.gov/medwatch.** You may also report side effects to Clovis Oncology, Inc. at 1-844-258-7662.

Click here for full Prescribing Information and additional Important Safety Information.

Rubraca ® ▼ (rucaparib) EU Authorized Use and Important Safety Information

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.

Rucaparib 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 two or more prior lines of platinum-based chemotherapy, and who are unable to tolerate further platinum-based chemotherapy.

Summary warnings and precautions: Haematological toxicity: Patients should not start Rubraca until they have recovered from haematological toxicities caused by previous chemotherapy (≤ CTCAE Grade 1). Complete blood count testing prior to starting treatment with Rubraca and monthly thereafter is advised. Rubraca should be interrupted or dose reduced and blood counts monitored weekly until recovery for the management of low blood counts. Myelodysplastic syndrome/acute myeloid leukaemia (MDS/AML): If MDS/AML is suspected, the patient should be referred to a haematologist for further investigation. If MDS/AML is confirmed, Rubraca should be discontinued. Photosensitivity: Patients should avoid spending time in direct sunlight as they may burn more easily. When outdoors, patients should wear protective clothing and sunscreen with SPF of 50 or greater. Gastrointestinal toxicities: Low grade (CTCAE Grade 1 or 2) nausea and vomiting may be managed with dose reduction or interruption. Additionally, antiemetics may be considered for treatment or prophylaxis.

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

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 to make Rubraca available to additional eligible patients. 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, the risk that results of further trials may differ from initial or interim results, or post-hoc analyses, as a result of many factors, including final results from a larger patient population differing from initial or interim results from a smaller patient population, and the uncertainties inherent in actions by the FDA, the EMA or other regulatory authorities regarding data required to support drug applications and whether to accept or approve drug applications that may be filed, as well as their decisions regarding drug labeling, reimbursement and pricing. 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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