NEWS RELEASE

Clovis Oncology to Highlight Expanded Data from Rubraca® (rucaparib) TRITON and ARIEL Clinical Programs in Prostate and Ovarian Cancers at the ESMO Congress 2019

9/12/2019

- Updated data from the Phase 2 TRITON2 trial of Rubraca in patients with advanced metastatic castration-resistant prostate cancer (mCRPC)
- Exploratory ARIEL3 analysis for Rubraca maintenance treatment regimen in ovarian cancer based on response to prior platinum-based chemotherapy
- Integrated safety analysis of Rubraca in ovarian cancer treatment and maintenance treatment settings

BOULDER, Colo.--(BUSINESS WIRE)-- Clovis Oncology, Inc. (NASDAQ: CLVS) today announced that three posters highlighting studies from the Rubraca® (rucaparib) clinical development program will be presented at the ESMO (European Society for Medical Oncology) Congress 2019, September 27 – October 1, 2019, in Barcelona, Spain.

The accepted abstracts summarize clinical trials in which Rubraca is being evaluated as a single agent in advanced ovarian and prostate cancers. These posters include updated results from the ongoing Phase 2 TRITON2 clinical trial of Rubraca in advanced mCRPC and additional analyses of data from the Study 10, ARIEL2 and ARIEL3 clinical trials in advanced ovarian cancer, which evaluated safety and efficacy in the treatment and maintenance settings.

The data from the TRITON2 trial will be presented in a poster by Professor Ray McDermott, Consultant Medical Oncologist, Tallaght University Hospital and Cancer Trials Ireland, and have been selected for inclusion in a poster discussion session on Sunday, September 29. TRITON2 is an ongoing international, multicenter, open-label, Phase 2 trial of Rubraca in men with advanced prostate cancer with a deleterious BRCA gene mutation (germline or somatic) or deleterious mutation in other homologous recombination repair genes in the metastatic castration-resistant setting.

“We look forward to presenting an updated look at the TRITON2 prostate cancer data at ESMO, with a primary focus on patient populations with a deleterious BRCA gene mutation, as well as mutations of other homologous

recombination repair genes," said Patrick J. Mahaffy, President and CEO of Clovis Oncology. "We continue to prepare to file a supplemental NDA for Rubraca in BRCA-mutant advanced prostate cancer by the end of the year."

In October 2018, Clovis Oncology announced that the U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy designation for Rubraca for the treatment of adult patients with BRCA1/2-mutated mCRPC who have received at least one prior androgen receptor-directed therapy and taxane-based chemotherapy.

Additional analyses of data from the Study 10, ARIEL2 and ARIEL3 clinical trials, which supported the European Union (EU) and FDA approvals of Rubraca for women with advanced ovarian cancer in the treatment and maintenance settings, will also be presented.

The three Rubraca abstracts from Clovis Oncology that have been accepted for either poster discussion or poster presentation at the ESMO Congress 2019 include:

Title: Preliminary results from the TRITON2 study of rucaparib in patients (pts) with DNA damage repair (DDR)-deficient metastatic castration-resistant prostate cancer (mCRPC): updated analyses (abstract 846PD)
Presenter: Professor Ray McDermott, Consultant Medical Oncologist, Tallaght University Hospital and Cancer Trials Ireland
Session: Poster discussion session, genitourinary tumors, prostate
Date/Time: Sunday 29 September, 08:30–09:45 CEST
Location: Malaga Auditorium (Hall 5)

As the subject of a poster discussion session, this poster will be on display for the duration of the congress in Hall 3 beginning at 07:30 CEST on Saturday, September 28 2019.

Title: Effect of response to last platinum-based chemotherapy in patients (pts) with platinum-sensitive, recurrent ovarian carcinoma in the Phase 3 study ARIEL3 of rucaparib maintenance treatment (abstract 1001P)
Presenter: Professor Jonathan A. Ledermann, UCL Cancer Institute, University College London and UCL Hospitals, London, UK
Session: Poster display session 2
Date/Time: Sunday 29 September, 12:00–13:00 CEST
Location: Poster Area (Hall 4)

Title: Integrated safety analysis of the poly (ADP-ribose) polymerase (PARP) inhibitor rucaparib in patients (pts) with ovarian cancer in the treatment and maintenance settings (abstract 1002P)
Presenter: Dr. Rebecca S. Kristeleit, University College London and UCL Hospitals, London, UK

Session: Poster display session 2
Date/Time: Sunday 29 September, 12:00–13:00 CEST
Location: Poster Area (Hall 4)

Specific program times and locations are subject to change by ESMO. Clovis Oncology's Rubraca poster presentations will be available online at **http://clovisoncology.com/pipeline/scientific-presentations** once they are presented at the meeting.

About Rubraca® (rucaparib)

Rubraca 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 U.S. FDA Approved Indications

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 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 ALT (74%), increase in 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 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

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 two or more 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:

Haematological toxicity

During treatment with Rubraca, events of myelosuppression (anaemia, 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 haematological 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 anaemia and neutropenia. Rubraca should be interrupted or dose reduced according to Table 1 (see section 4.2) 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 haematologist for further investigations.

Myelodysplastic syndrome/acute myeloid leukaemia

Myelodysplastic syndrome/acute myeloid leukaemia (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 haematologist for further investigations, including bone marrow analysis and blood sampling for cytogenetics. If, following investigation for prolonged haematological 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 (SPF) of 50 or greater.

Gastrointestinal toxicities

Gastrointestinal toxicities (nausea and vomiting) are frequently reported with Rubraca, are generally low grade (CTCAE Grade 1 or 2),and may be managed with dose reduction (refer to Table 1) 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 hospitalisation.

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 section 5.3).

Pregnancy/contraception

Pregnant women should be informed of the potential risk to a foetus. 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). A pregnancy test before initiating treatment is recommended in women of reproductive potential.

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, for those indications that require them, 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, with additional office locations in the U.S. and Europe. Please visit **www.clovisoncology.com** for more information.

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. 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, whether future study results will be consistent with study findings to date and whether future study results will support continued development or regulatory approval. 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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Clovis Investor Contacts:

Anna Sussman, 303.625.5022
asussman@clovisoncology.com
or
Breanna Burkart, 303.625.5023
bburkart@clovisoncology.com

Clovis Media Contacts:

U.S.

Lisa Guiterman, 301.217.9353
clovismedia@sambrown.com
or
Christy Curran, 615.414.8668
clovismedia@sambrown.com

EU
Jake Davis, +44 (0) 20.3946.3538
Jake.Davis@publicisresolute.com

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