NEWS RELEASE

Clovis Oncology Announces Presentations at 2019 ASCO Annual Meeting

5/16/2019

Accepted abstracts highlight additional data from phase 3 ARIEL3 clinical trial, genomic data from phase 2 TRITON2 clinical trial, and the designs of other ongoing rucaparib trials

BOULDER, Colo.--(BUSINESS WIRE)-- Clovis Oncology, Inc. (NASDAQ: CLVS) today announced that four abstracts featuring data for Rubraca® (rucaparib) and ongoing studies in multiple tumor types will be presented at the 2019 American Society of Clinical Oncology (ASCO) Annual Meeting taking place May 31 – June 4 in Chicago.

The accepted abstracts summarize clinical trials in which Rubraca is being evaluated as a single agent and as combination therapy with nivolumab in a variety of solid tumor types including ovarian, prostate, biliary tract and endometrial cancers. These include additional genomic profiling data from TRITON2, and new data from extended follow up of patients in ARIEL3.

“Increased understanding about the role of genomic mutations, as well as the growing number and type of oncology therapies, offer tremendous potential for us to more precisely target and improve treatment of the most challenging cancers,” said Patrick J. Mahaffy, President and CEO of Clovis Oncology. “In our own clinical development program and in investigator-led studies, we are evaluating the utility of Rubraca in multiple solid tumor types where there is genomic rationale, including among patients with BRCA1/2 mutations as well as mutations in other genes that play a role in DNA repair.”

The two Clovis Oncology-sponsored abstracts accepted for presentation at the 2019 ASCO Annual Meeting comprise:

Abstract 5031 (Poster Board #143) - Genomic characteristics of deleterious BRCA1 and BRCA2 alterations and associations with baseline clinical factors in patients with metastatic castration-resistant prostate cancer enrolled in TRITON2

- Presenter: Wassim Abida, MD, PhD
- Session: Genitourinary (Prostate) Cancer
- Date/Time: Saturday, June 1, 1:15-4:15 p.m. Central Daylight Time (CDT)
- Location: Hall A

Abstract 5522 (Poster Board #345) - Exploratory analysis of the effect of maintenance rucaparib on post-progression outcomes in patients with platinum-sensitive recurrent ovarian carcinoma and updated safety data from the phase 3 study ARIEL3

- Presenter: Robert L. Coleman, MD, FACOG, FACS
- Session: Gynecologic Cancer
- Date/Time: Saturday, June 1, 1:15-4:15 p.m. CDT
- Location: Hall A

This poster (abstract #5522) will be discussed at the associated poster discussion session on Saturday, June 1, 4:30-6:00 p.m. CDT in Room S406.

The two Clovis-sponsored posters will be available online at **http://clovisoncology.com/pipeline/scientific-presentations/** once they are presented at the meeting.

Additionally, two investigator-sponsored abstracts describing combination studies of Rubraca and nivolumab trials in progress are also being presented:

Abstract TPS2663 (Poster Board #297b) - A phase Ib/IIa study of rucaparib (PARP inhibitor) combined with nivolumab in metastatic castrate-resistant prostate cancer and advanced/recurrent endometrial cancer

- Presenter: Raanan Alter, MD
- Session: Developmental Immunotherapy and Tumor Immunobiology
- Date/Time: Saturday, June 1, 8:00-11:00 a.m. CDT
- Location: Hall A

Abstract TPS4153 (Poster Board #252a) - A multi-center phase II trial of rucaparib in combination with nivolumab as maintenance therapy for patients with advanced biliary tract cancer

- Presenter: Vaibhav Sahai, MD
- Session: Gastrointestinal (Noncolorectal) Cancer
- Date/Time: Monday, June 3, 8:00-11:00 a.m. CDT
- Location: Hall A

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 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 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 or 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, 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. Examples of forward-looking statements contained in this press release include, among others, statements regarding our plans for commercial launch in additional countries, expectations for submission of regulatory filings, our expectations regarding ongoing or planned trials and the timing and pace of commencement of and enrollment in our clinical trials, including those being considered, planned or conducted in collaboration with partners. 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 and whether future study results will support continued development or regulatory approval, the corresponding development pathways of our companion diagnostics, the timing of availability of data from our clinical trials and the results, the initiation, enrollment, timing and results of our planned clinical trials. 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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