NEWS RELEASE

Clovis Oncology's Rubraca® (rucaparib) Granted FDA Priority Review for Advanced Prostate Cancer

1/15/2020

- Clovis seeks U.S. approval for rucaparib as monotherapy treatment for patients with BRCA1/2-mutant recurrent, metastatic castrate-resistant prostate cancer

- FDA submission based on data from TRITON clinical program in advanced prostate cancer

- FDA has assigned PDUFA date of May 15, 2020

BOULDER, Colo.--(BUSINESS WIRE)-- Clovis Oncology, Inc. (NASDAQ: CLVS) announced today that the U.S. Food and Drug Administration (FDA) has accepted the company's supplemental New Drug Application (sNDA) for Rubraca® (rucaparib) and granted priority review status to the application with a Prescription Drug User Fee Act (PDUFA) date of May 15, 2020. Clovis submitted the sNDA submission for rucaparib as a monotherapy treatment of adult patients with BRCA1/2-mutant recurrent, metastatic castrate-resistant prostate cancer in November 2019.

"Recently presented data suggests that Rubraca may play a meaningful role in the treatment of patients with BRCA1/2-mutant recurrent, metastatic castrate-resistant prostate cancer, and this filing represents an important milestone for Clovis as it brings us one step closer to potentially making this valuable therapy available," said Patrick J. Mahaffy, President and CEO of Clovis Oncology. "We are encouraged by the FDA's decision to grant priority review to the Rubraca application, which focuses on eligible patients with advanced prostate cancer, for whom new treatment options are very much needed."

A priority review designation is granted to proposed medicines that the FDA has determined have the potential, if approved, to offer a significant improvement in the safety or effectiveness of the treatment, prevention or diagnosis of a serious condition. Priority designation shortens the review period from the standard 10 months to six months.

About Prostate Cancer

The American Cancer Society estimated that more than 175,000 men in the United States would be diagnosed with prostate cancer in 2019, and the GLOBOCAN Cancer Fact Sheets estimated that approximately 450,000 men in Europe were diagnosed with prostate cancer in 2018. Castrate-resistant prostate cancer has a high likelihood of developing metastases. Metastatic castrate-resistant prostate cancer, or mCRPC, is an incurable disease, usually associated with poor prognosis. Approximately 43,000 men in the U.S. are expected to be diagnosed with mCRPC in 2020. According to the American Cancer Society, the five-year survival rate for mCRPC is approximately 30 percent. Up to 12 percent of patients with mCRPC harbor a deleterious germline and/or somatic mutation in the genes BRCA1 and BRCA2. These molecular markers may be used to select patients for treatment with a PARP inhibitor.

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.

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 expectation of timing for review and approval of the sNDA and submission, and availability of Rucaparib to the patients with advanced prostate cancer. 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 actions by the FDA, the EMA or other regulatory authorities regarding whether to approve drug applications that may be filed, as well as their decisions that may affect drug labeling, pricing and reimbursement, the final approved label for the prostate indication, and our assumptions and expectations regarding the size of the patient population, and other matters that could affect the availability or commercial potential of our drug candidates or companion diagnostics. 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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