NEWS RELEASE

Journal of Clinical Oncology Publishes Additional Data from Clovis Oncology's TRITON2 Clinical Trial Evaluating Rubraca® (rucaparib) for the Treatment of mCRPC in Patients with BRCA1/2 Gene Mutations

8/17/2020

BOULDER, Colo.--(BUSINESS WIRE)-- Clovis Oncology, Inc. (NASDAQ: CLVS), announced today that data from the Phase 2 TRITON2 study of Rubraca® (rucaparib) for the treatment of metastatic castration-resistant prostate cancer (mCRPC) harboring BRCA1/2 mutations were published online in the Journal of Clinical Oncology. These results supported the May 2020 U.S. Food and Drug Administration (FDA) accelerated approval of Rubraca for the treatment of mCRPC patients who have a deleterious BRCA mutation (germline and/or somatic) and who have previously received androgen receptor-directed therapy and taxane-based chemotherapy.

"Through publication in this prestigious journal, we are pleased to be able to share more detail about this important study, which we believe will be helpful for physicians as they consider treatment options for their mCRPC patients," said Patrick J. Mahaffy, President and CEO of Clovis Oncology. "The TRITON2 data underscore Rubraca's role as a meaningful new treatment option for men with mCRPC and a deleterious germline or somatic BRCA mutation who have progressed on androgen receptor-directed therapy and taxane-based chemotherapy."

The publication, titled Rucaparib in Men with Metastatic Castration-resistant Prostate Cancer Harboring a BRCA1 or BRCA2 Gene Alteration, is available online at **https://ascopubs.org/journal/jco/** and can be accessed by **clicking here**.

"PARP inhibitors have been a welcome additional treatment option available for eligible mCRPC patients, and I'm pleased that this publication provides additional detail about the potential clinical benefit of Rubraca for patients," said Wassim Abida, M.D., Medical Oncologist, Memorial Sloan Kettering Cancer Center, and principal investigator for the TRITON2 study. "These additional data presented in this publication provide physicians important information to inform treatment decisions for their eligible patients."

Dr. Abida has provided advisory services for Clovis.

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. Clovis holds worldwide rights for Rubraca.

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

Rubraca U.S. FDA Approved mCRPC Indication

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) has occurred 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. In TRITON2, MDS/AML was not observed in patients with mCRPC (n=209) regardless of homologous recombination deficiency (HRD) mutation.

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 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 findings in genetic toxicity and animal reproduction studies, advise male patients with female partners of reproductive potential or who are pregnant to use effective methods of contraception during treatment and for 3 months following last dose of Rubraca. Advise male patients not to donate sperm during therapy and for 3 months following the last dose of Rubraca.

Most common adverse reactions in TRITON2 (≥ 20%; Grade 1-4) were fatigue/asthenia (62%), nausea (52%), anemia (43%), AST/ALT elevation (33%), decreased appetite (28%), rash (27%), constipation (27%), thrombocytopenia (25%), vomiting (22%), and diarrhea (20%).

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.

Click here for full Prescribing Information for Rubraca.

You may also report side effects to Clovis Oncology, Inc. at 1-415-409-7220 (US toll) or 1-844-CLVS-ONC (1-844-258-7662; US toll-free).

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.

This press release contains forward-looking statements (as defined under the Private Securities Litigation Reform Act of 1995) about the potential of Rubraca® (rucaparib) for the treatment of adult patients with 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, and reflects Clovis Oncology's current beliefs. As with any pharmaceutical product, there are substantial risks and uncertainties in the process of development and commercialization that could cause actual results to differ materially from those expressed or implied by the forward-looking statements. In particular, there are no guarantees that future study

results and patient experience will be consistent with the study findings to date, that Rubraca will receive regulatory approval for any future indications, or that it will prove to be commercially successful. 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. All forward-looking statements are based on information currently available to the company, and Clovis Oncology does not undertake to update or revise any forward-looking statements

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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

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