



NEWS RELEASE

Clovis Oncology Announces New Recommendations for Rubraca® (rucaparib) Tablets in Updated National Comprehensive Cancer Network (NCCN) Guidelines® for the Treatment of Metastatic Castration-Resistant Prostate Cancer (mCRPC)

5/28/2020

Rubraca recommended as a treatment option for BRCA-mutant mCRPC in the second line setting and as a subsequent therapy; if the patient is not fit for chemotherapy, rucaparib can be considered prior to taxane

BOULDER, Colo.--(BUSINESS WIRE)-- Clovis Oncology, Inc. (NASDAQ: CLVS), announced today that the National Comprehensive Cancer Network®(NCCN) updated its Clinical Practice Guidelines in Oncology for Prostate Cancer to include new recommendations for Rubraca® (rucaparib) tablets. In addition to its ovarian cancer recommendations, Rubraca is now recommended in the NCCN Guidelines® for the treatment of BRCA-mutant patients with mCRPC under second-line treatment and subsequent therapy as a Category 2A recommendation inclusive of the following:

Rucaparib is a treatment option for patients with mCRPC and a pathogenic BRCA1 or BRCA2 mutation (germline and/or somatic) who have been treated with androgen receptor-directed therapy and a taxane-based chemotherapy. If the patient is not fit for chemotherapy, rucaparib can be considered even if taxane-based therapy has not been given.

“We are pleased that the NCCN has acknowledged the importance of novel targeted therapies for the treatment of advanced prostate cancer, and the need for new treatment options for patients with BRCA mutations, including Rubraca, the first PARP inhibitor approved for these patients,” said Patrick J. Mahaffy, President and CEO of Clovis Oncology. “In particular, in the current COVID-19 environment, many patients would prefer to avoid chemotherapy, which requires frequent clinical visits, in favor of an oral agent that can be delivered directly to and taken at home.”

NCCN Guidelines are the recognized standard for clinical direction and policy in cancer care and are the most thorough and frequently updated clinical practice guidelines available in any area of medicine.ⁱⁱ The NCCN prostate cancer panel's decision to include Rubraca as a Category 2A preferred option for the treatment of patients with a BRCA mutation for second-line treatment and subsequent therapy was based on the results of the Phase 2 TRITON2 study.

About Prostate Cancer

The American Cancer Society estimates that nearly 192,000 men in the United States will be diagnosed with prostate cancer in 2020ⁱⁱⁱ, and the GLOBOCAN Cancer Fact Sheets estimated that approximately 450,000 men in Europe were diagnosed with prostate cancer in 2018.^{iv} Castration-resistant prostate cancer has a high likelihood of developing metastases. Metastatic castration-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.^v According to the American Cancer Society, the five-year survival rate for mCRPC is approximately 30 percent.^{vi} Approximately 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.^{vii}

Rubraca U.S. FDA Approved 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 (\leq 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 ($\geq 20\%$; 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 Accessing Rubraca

Rubraca is available in the United States through specialty pharmacies and distributors. Clovis is committed to ensuring Rubraca access for patients and offers eligible patients financial and reimbursement support through Rubraca Connections. More information about Rubraca Connections is available at **RubracaConnections.com** or by calling 1-844-779-7707 between 8 a.m. and 8 p.m. Eastern Time, Monday through Friday.

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.

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

i NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Prostate Cancer V.2.2020. Accessed May 21, 2020.

ii NCCN website. About NCCN Guidelines. <https://www.nccn.org/professionals/default.aspx>. Accessed May 27, 2020.

iii American Cancer Society. Key Statistics for Prostate Cancer. <https://www.cancer.org/cancer/prostate-cancer/about/key-statistics.html>. Accessed January 30, 2020.

iv GLOBOCAN Cancer Fact Sheets: prostate cancer. Prostate Cancer Estimated Incidence, Mortality and Prevalence Worldwide in 2018. <https://gco.iarc.fr/today/data/factsheets/cancers/27-Prostate-fact-sheet.pdf>. Accessed February 4, 2020.

v Cameron A. Wade and Natasha Kyprianou. Profiling Prostate Cancer Therapeutic Resistance. International Journal of Molecular Sciences. 2018, 19, 204. <https://www.mdpi.com/1422-0067/19/3/904/pdf>.

vi American Cancer Society. Survival rates for prostate cancer. <https://www.cancer.org/cancer/prostate-cancer/detection-diagnosis-staging/survival-rates.html>. Accessed February 4, 2020.

vii Abida W, Armenia J, Gopalan A, et al. Prospective Genomic Profiling of Prostate Cancer Across Disease States Reveals Germline and Somatic Alterations That May Affect Clinical Decision Making. JCO Precis Oncol 2017: 1-16.

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