



NEWS RELEASE

Clovis Oncology to Highlight Data at ASCO 2021 Genitourinary Cancers Symposium Virtual Meeting

2/4/2021

BOULDER, Colo.--(BUSINESS WIRE)-- Clovis Oncology, Inc. (NASDAQ: CLVS) announced today that two abstracts featuring data from clinical studies evaluating Rubraca® (rucaparib) in metastatic castration-resistant prostate cancer (mCRPC) and one abstract describing adverse events associated with mCRPC treatment based on real world evidence have been accepted for poster presentation at the American Society of Clinical Oncology (ASCO) 2021 Genitourinary Cancers Symposium to be held virtually, February 11-13, 2021.

"These data underscore our continued commitment to fully understanding the clinical role of Rubraca and to accelerating the delivery of transformative therapies to the advanced prostate cancer community," said Patrick J. Mahaffy, President and CEO of Clovis Oncology. "The data that will be shared add to growing scientific knowledge about the science of mCRPC and broaden our understanding of Rubraca as a treatment option for patients diagnosed with mCRPC."

The following Clovis-sponsored abstracts will be available on February 8 at 5:00 pm ET and will also be available as posters for viewing starting February 11 at 8:00 am ET on **ASCO's Meeting Library**. The posters can also be viewed at <https://www.clovisoncology.com/pipeline/scientific-presentations/> starting February 11 at 8:00 am ET.

Abstract Number 80: Association of co-occurring gene alterations and clinical activity of rucaparib in patients with BRCA1 or BRCA2 mutated (BRCA+) metastatic castration-resistant prostate cancer (mCRPC)

- Poster Session: Prostate Cancer - Advanced Disease
- Date/Time: Thursday, February 11 at 8:00 am ET
- Lead Author: Wassim Abida, MD, PhD, Memorial Sloan Kettering Cancer Center, New York, New York

Abstract Number 79: Rucaparib plus enzalutamide in patients (pts) with metastatic castration-

resistant prostate cancer (mCRPC): Pharmacokinetics (PK) and safety data from the phase 1b RAMP study

- Poster Session: Prostate Cancer - Advanced Disease
- Date/Time: Thursday, February 11 at 8:00 am ET
- Lead Author: Arpit Rao, MBBS, University of Minnesota Medical School, Minneapolis, Minnesota

Abstract Number 61: Clinically significant events associated with metastatic castration-resistant prostate cancer (mCRPC) treatments

- Poster Session: Prostate Cancer - Advanced Disease
- Date/Time: Thursday, February 11 at 8:00 am ET
- Lead Author: Kelvin A. Moses, MD, PhD, FACS, Vanderbilt University Medical Center, Nashville, Tennessee

About Rubraca (rucaparib)

Rubraca is an oral, small molecule inhibitor of PARP1, PARP2 and PARP3 being developed multiple tumor types, including ovarian and 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 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. Select patients for therapy based on an FDA-approved companion diagnostic for Rubraca.

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 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, 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, and has additional offices in the U.S. and Europe.

Please visit [clovisoncology.com](https://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 expectations for submission of regulatory filings, the timing and pace of commencement of and enrollment in our clinical trials, including those being planned or conducted in collaboration with partners, the potential results of such clinical trials, our expectations regarding the suitability of Rubraca for, and our plans to develop Rubraca in, additional indications and tumor types. 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, the timing of availability of data from our clinical trials and the initiation, enrollment, timing and results of our planned clinical trials and the corresponding development pathways, effectiveness and suitability of diagnostic tests, the risk that final results of ongoing trials may differ from initial or interim results as a result of factors such as final results from a larger patient population may be different from initial or interim results from a smaller patient population, the risk that additional pre-clinical or clinical studies may not support further development in certain additional indications or tumor types, and actions by the FDA, the EMA or other regulatory authorities regarding data required to support drug applications and whether to approve drug applications. 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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