NEWS RELEASE

Clovis Oncology Highlights Rubraca® (rucaparib) Clinical Data at AACR Virtual Annual Meeting 2021

4/10/2021

- Findings from the Phase 1b RAMP study evaluating the combination of Rubraca and Xtandi® (enzalutamide) in men with unselected mCRPC lay the groundwork for the Phase 3 CASPAR study which is expected to begin enrolling patients shortly
- Phase 1 data from the RUCA-J study of Rubraca in Japanese patients with advanced solid tumors show similar safety and pharmacokinetic profiles to those observed in Western patients

BOULDER, Colo.--(BUSINESS WIRE)-- Clovis Oncology, Inc. (NASDAQ: CLVS) announced that Phase 1 clinical data from studies exploring Rubraca in combination with Xtandi for the treatment of advanced prostate cancer (RAMP) and Rubraca monotherapy in advanced solid tumors in Japanese patients (RUCA-J) will be presented during week one of the American Association for Cancer Research Virtual Annual Meeting (AACR), taking place April 10-15, 2021.

“We remain committed to understanding how Rubraca may benefit patients with cancer, and the data presented at AACR further enhance our understanding in different patient populations and solid tumor types,” said Patrick J. Mahaffy, President and CEO of Clovis Oncology. “The Phase 1b RAMP data for the combination of Rubraca and Xtandi in unselected mCRPC patients help inform the Alliance for Clinical Oncology-sponsored CASPAR Phase 3 trial which is expected to begin enrolling patients soon, and we look forward to learning more about the combination.”

Following are details of the Clovis-sponsored presentations at AACR 2021:

Poster Presentation 445: Genomic Characteristics and Response to Rucaparib and Enzalutamide in the Phase 1b RAMP Study of Metastatic Castration-Resistant Prostate Cancer (mCRPC) Patients

- Lead author: Arpit Rao, MBBS, University of Minnesota, Minneapolis, USA
- Session: Clinical Research
- Date/Time: April 10, 2021, 8:30 a.m. - 11:59 p.m. ET
- Key Takeaways: The results of this study demonstrated that unselected patients with mCRPC who had progressed on androgen receptor (AR)-directed therapies reported declines in prostate-specific antigen (PSA) following treatment with a combination of rucaparib 600 mg twice daily and enzalutamide 160 mg once daily, and these declines were observed even in the presence of AR alterations and the absence of DNA damage repair gene alterations. The safety profile was consistent with that associated with each drug as a monotherapy, with no clinically significant drug-drug interactions observed with the combination. These data support further study of the combination in this patient population and the Phase 3 CASPAR study (Alliance A031902; NCT04455750) is expected to begin enrolling biomarker-unselected patients with mCRPC shortly.

Poster Presentation CT124: Evaluation of Rucaparib in Japanese Patients with a Previously Treated Advanced Solid Tumor

- Lead author: Kenji Tamura, MD, PhD, National Cancer Center Hospital, Tokyo, Japan
- Session: Phase I Clinical Trials
- Date/Time: April 10, 2021, 8:30 a.m. - 11:59 p.m. ET
- Key Takeaways: This study suggests rucaparib 600 mg taken twice daily had a manageable safety profile for Japanese patients with advanced solid tumors, including ovarian, prostate, endometrial, and pancreatic cancer. The pharmacokinetic profile of rucaparib in Japanese patients overlapped with that of Western patients. Among patients with measurable disease, 18.5% (5/27) achieved an objective response rate and 51.9% (14/27) had stable disease per RECIST v1.1. These results support further exploration of rucaparib 600 mg twice daily in Japanese patients.

The presentations can also be viewed at **https://www.clovisoncology.com/pipeline/scientificpresentations/** .

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

Ovarian Cancer

Rubraca is indicated for the maintenance treatment of adult women 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 for the treatment of adult women with a deleterious BRCA mutation (germline and/or somatic)-associated epithelial ovarian, fallopian tube, or primary peritoneal cancer who have been treated with two or more chemotherapies. Select patients for therapy based on an FDA-approved companion diagnostic for Rubraca.

Prostate Cancer

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. Patients should be identified for treatment with Rubraca based on the presence of a deleterious BRCA mutation (germline and/or somatic) and selected 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) occur 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 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. For males on Rubraca treatment who have female partners of reproductive potential or who are pregnant,

effective contraception should be used during treatment and for 3 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 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 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.

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.

Please **click here** for full Prescribing Information for Rubraca.

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.

About CASPAR Clinical Trial

The CASPAR study is sponsored by the Alliance for Clinical Trials in Oncology (Alliance A031902; NCT04455750) and

will enroll approximately 1,000 patients in the United States. It is expected to open at hundreds of National Clinical Trials Network (NCTN) sites nationally. This is the only combination trial of a PARP inhibitor and novel anti-androgen with an overall survival co-primary endpoint. Patients who have received prior abiraterone/apalutamide in a non-mCRPC setting are allowed to enroll to maximize applicability in the era of rapidly changing standards-of-care. The Alliance is part of the NCTN sponsored by the National Cancer Institute (NCI).

About Alliance for Clinical Trials in Oncology

The Alliance for Clinical Trials in Oncology develops and conducts clinical trials with promising new cancer therapies, and utilizes the best science to develop optimal treatment and prevention strategies for cancer, as well as research methods to alleviate side effects of cancer and cancer treatments. The Alliance is part of the National Clinical Trials Network (NCTN) sponsored by the National Cancer Institute (NCI) and serves as a research base for the NCI Community Research Oncology Program (NCORP). The Alliance comprises nearly 10,000 cancer specialists at hospitals, medical centers, and community clinics across the United States and Canada. Learn more about the Alliance, visit **www.AllianceforClinicalTrialsinOncology.org**.

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 the potential results of such clinical trials, our expectations regarding the suitability of Rubraca for certain patient populations or indications, and our plans to develop Rubraca in additional indications and tumor types, and our expectations regarding the outcomes of early studies or trials supporting further development, both non-clinical and clinical. 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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