NEWS RELEASE

Clovis Oncology Presents Data in Advanced Prostate Cancer at ASCO 2021 Genitourinary Cancers Symposium Virtual Meeting

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- Findings from Phase 1b RAMP clinical trial lay the groundwork for Phase 3 CASPAR clinical trial evaluating Rubraca® (rucaparib) and Xtandi® (enzalutamide) in combination which is expected to begin enrolling patients shortly
- Exploratory analyses from the Phase 2 TRITON2 study demonstrate the efficacy of Rubraca in men with BRCA-mutated mCRPC despite the presence of co-occurring gene alterations in certain tumor-suppressor genes that are associated with poor prognosis

BOULDER, Colo.--(BUSINESS WIRE)-- Clovis Oncology, Inc. (NASDAQ: CLVS) today announced Rubraca data being presented at the American Society for Clinical Oncology (ASCO) Genitourinary Cancers Virtual Symposium 2021. These include data from the Phase 1b RAMP study evaluating Rubraca in combination with Xtandi, exploratory analyses from the pivotal TRITON2 study, and an analysis evaluating the rates of adverse events for different metastatic castration-resistant prostate cancer (mCRPC) treatments in a population of insured patients in the United States.

“We are pleased to share these data with the medical and scientific community to inform choices related to mCRPC treatment. The research into co-occurring alterations in mCRPC patients with a mutation of BRCA underscores the importance of genomic testing in men with mCRPC,” said Patrick J. Mahaffy, President and CEO of Clovis Oncology. “Additionally, we are encouraged by the results from the RAMP study, which lay the groundwork for the Phase 3 CASPAR clinical trial sponsored by the Alliance for Clinical Trials in Oncology evaluating Rubraca and Xtandi as a novel combination therapy in men with first-line metastatic castration-resistant prostate cancer.”

Data from the RAMP study are presented by Arpit Rao, MD, Assistant Professor, Hematology, Oncology and Transplantation at the University of Minnesota. This Phase 1b study is investigating the combination of Rubraca and Xtandi in biomarker-unselected (including BRCA1/2 mutation negative) patients with mCRPC to assess the

pharmacokinetics (PK) and safety of the combination. Treatment with rucaparib and enzalutamide had no clinically significant effect on the PK profiles of either drug, and the safety profile of the combination was consistent with that associated with each drug as monotherapy. The results presented at ASCO GU show that this combination is well-tolerated and without any significant drug-drug interactions. Data from the RAMP study support the randomized, placebo-controlled Phase 3 CASPAR study (Alliance A031902; NCT04455750) that is studying Rubraca and Xtandi, and is the subject of a Trial in Progress (TiP) poster being presented at the ASCO GU meeting. It is expected to begin enrolling mCRPC patients shortly.

The CASPAR study is sponsored by the Alliance for Clinical Trials in Oncology 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).

Data from the TRITON2 clinical trial are presented by Wassim Abida MD, PhD at Memorial Sloan Kettering Cancer Center. These data underscore the antitumor activity of Rubraca among men with BRCA-mutated mCRPC and commonly co-occurring genomic alterations. Alterations in tumor suppressor genes, including TP53, PTEN and RB1, are associated with poor prognosis in patients with prostate cancer. Results from TRITON2 showed antitumor activity for Rubraca in patients with BRCA-mutated mCRPC associated with or without co-occurring alterations in these genes. There was no clear difference in radiographic and PSA response rates for patients with or without co-occurring TP53, PTEN, or RB1 alterations. Based on these results, researchers concluded that patients with mCRPC associated with a BRCA alteration should be considered for treatment with rucaparib irrespective of the presence of co-occurring alterations in these tumor suppressor genes.

In addition, data from an analysis of clinically significant events (CSEs) associated with mCRPC treatments were presented by Kelvin A. Moses, MD, PhD, Associate Professor of Urology at Vanderbilt University Medical Center. Researchers designed the analysis to better understand the association between mCRPC treatments and development of CSEs in a population of insured patients in the United States. Using an administrative claims database for the period from January 2008 to March 2019, the analysis found that among available mCRPC treatments, chemotherapy-based regimens had the highest CSE rates per treatment year. These data indicate the burden of treatment for patients and can inform treatment decisions.

Clovis Oncology-sponsored e-posters are available online at **www.clovisoncology.com/pipeline/scientific-presentations**.

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 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. 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 (≤ 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.

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 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**.

Clovis Oncology Forward-Looking Statement

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 the timing and pace of commencement of and enrollment in clinical trials, including those not sponsored by us, 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, 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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