Clovis Oncology Announces Presentations at 2017 ASCO Annual Meeting

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Updates on rucaparib clinical trials in multiple solid tumors and therapy settings at ASCO Annual Meeting; top-line data from ARIEL3 pivotal study anticipated by end of June

BOULDER, Colo.--(BUSINESS WIRE)--May 23, 2017-- Clovis Oncology, Inc. (NASDAQ: CLVS) today announced that abstracts highlighting progress in the rucaparib clinical development program will be presented at the 2017 American Society of Clinical Oncology (ASCO) Annual Meeting taking place June 2-6 in Chicago.

Four abstracts highlighting ongoing rucaparib clinical trials will showcase some of the multiple cancer types in which the compound is being studied, including germline and somatic BRCA-mutated, relapsed, high-grade ovarian cancer; metastatic castration-resistant prostate cancer associated with homologous recombination deficiency; and HER2 negative metastatic breast cancer.

“The abstracts being presented at ASCO 2017 highlight the depth of our clinical program exploring the potential of rucaparib as a precision medicine therapeutic for multiple cancer types,” said Patrick J. Mahaffy, President and CEO of Clovis Oncology. “The oncology community has taken great interest in PARP inhibitors and the role of these novel therapeutics within the cancer treatment paradigm. We are pleased to describe these current clinical studies evaluating rucaparib in various solid tumor settings at this prestigious meeting, and importantly, we look forward to announcing the top-line results from ARIEL3 in the ovarian cancer maintenance treatment setting by the end of June.”

Rucaparib is Clovis Oncology’s oral, potent, small-molecule inhibitor of PARP1, PARP2 and PARP3. In December 2016, the FDA approved rucaparib (Rubraca®) tablets as monotherapy for women with advanced ovarian cancer who have been treated with two or more chemotherapies and whose tumors have a deleterious *BRCA* mutation (germline and/or somatic) as identified by an FDA-approved companion diagnostic test.

The ARIEL3 pivotal study of rucaparib is a randomized, double-blind study comparing the effects of rucaparib against placebo to evaluate whether rucaparib given as a maintenance treatment to platinum-sensitive ovarian cancer patients can extend the period of time for which the disease is controlled after a response to platinum-based chemotherapy. Top-line results from ARIEL3 are anticipated by the end of June, and the Company plans to provide a more comprehensive presentation of the ARIEL3 results in a scientific session at a medical meeting later this year. Pending positive data, the Company intends to submit a supplemental New Drug Application (NDA) for a second line or later maintenance treatment indication within approximately four months of the database lock.

The three trials-in-progress abstracts accepted for presentation at the 2017 ASCO Annual Meeting comprise:

Abstract TPS5603 (Poster #423b) – ARIEL4: An International, Multicenter Randomized Phase 3 Study of the PARP Inhibitor Rucaparib vs Chemotherapy in Germline or Somatic *BRCA1*- or *BRCA2*-Mutated, Relapsed, High-Grade Ovarian Carcinoma

- Presenter: Amit M. Oza, MD, Princess Margaret Cancer Centre, University Health Network
- Session: Gynecologic Cancer
- Date/Time: Saturday, June 3, 1:15-4:45 p.m. CDT
- Location: Hall A

Abstract TPS1117 (Poster #103b) – An open-label, phase II study of rucaparib, a PARP inhibitor, in HER2 negative metastatic breast cancer patients with high genomic loss of heterozygosity: RUBY.

- Presenter: Anne Patsouris, MD, Institute of West Cancerology Paul Papin
- Session: Breast Cancer-Metastatic

- Date/Time: Sunday, June 4, 8:00-11:30 a.m. CDT
- Location: Hall A

Abstract TPS5087 (Poster #160b) – Trial of RucaparIb in ProsTate IndicatiONs 3 (TRITON3): An International, Multicenter, Randomized, Open-Label Phase 3 Study of Rucaparib vs Physician's Choice of Therapy for Patients (Pts) with Metastatic Castration-Resistant Prostate Cancer (mCRPC) Associated with Homologous Recombination Deficiency (HRD)

- Presenter: Charles J. Ryan, MD, University of California San Francisco Helen Diller Family Comprehensive Cancer Center
- Session: Genitourinary (Prostate) Cancer
- Date/Time: Monday, June 5, 1:15-4:45 p.m. CDT
- Location: Hall A

Additionally, Clovis' companion diagnostics collaborator Foundation Medicine will present results from a genomic-profiling study:

Abstract 5512 (Oral #5512) – Comprehensive genomic profiling (CGP) with loss of heterozygosity (LOH) to identify therapeutically relevant subsets of ovarian cancer (OC)

- Presenter: Julia Andrea Elvin, MD PhD, Foundation Medicine, Inc.
- Session: Clinical Science Symposium
- Date/Time: Monday, June 5, 8:48-9:00 a.m. CDT
- Location: E450ab

Clovis' rucaparib posters will be available online at http://clovisoncology.com/pipeline/scientific-presentations/ as of the time they are presented at the meeting.

About Rucaparib

Rucaparib is an oral, small molecule inhibitor of PARP1, PARP2 and PARP3 being developed in ovarian cancer as well as several additional solid tumor indications. The MAA submission in Europe for an ovarian cancer treatment indication was submitted and accepted during the fourth quarter of 2016. Additionally, rucaparib is being developed as maintenance treatment for ovarian cancer in the ARIEL3 trial for patients with tumors with BRCA mutations and other DNA repair deficiencies beyond BRCA, as well as biomarker negative patients. Topline results from ARIEL3 are expected by late June, which, pending positive data, is expected to be followed by the submission of a sNDA for a second line or later maintenance treatment indication. Rucaparib is also being developed in patients with mutant BRCA tumors and other DNA repair deficiencies beyond BRCA – commonly referred to as homologous recombination deficiencies, or HRD. Studies open for enrollment or under consideration include prostate, breast, pancreatic, gastroesophageal, bladder and lung cancers. Clovis holds worldwide rights for rucaparib.

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 San Francisco, California and Cambridge, UK. Please visit 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 made

pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. 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 the clinical development programs for our drug candidates, including the result of clinical trials, whether future study results will be consistent with study findings to-date, the corresponding development pathways of our companion diagnostics, the timing of availability of data from our clinical trials and the results of our clinical trials, the initiation, enrollment and timing of our planned clinical trials, actions by the FDA, the EMA or other regulatory authorities regarding whether to approve drug applications that may be filed, as well as their decisions that may affect drug labeling, pricing and reimbursement, and other matters that could affect the availability or commercial potential of our drug candidates or companion diagnostics. 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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