Clovis Oncology to Present Comprehensive Dataset from Successful ARIEL3 Clinical Trial Program at 2017 ESMO Congress

August 30, 2017 8:00 AM ET

- **Comprehensive results from Phase 3 ARIEL3 maintenance treatment trial of rucaparib in advanced ovarian cancer patients accepted as late-breaker presentation, will be highlighted in ESMO press program**
- **Posters outlining the designs of the ARIEL4 and TRITON clinical trial programs will also be presented**

BOULDER, Colo.--(BUSINESS WIRE)--Aug. 30, 2017-- Clovis Oncology, Inc. (NASDAQ: CLVS) today announced that abstracts highlighting progress in the rucaparib clinical development program will be presented at the 2017 European Society for Medical Oncology (ESMO) Congress taking place September 8-12, 2017 in Madrid, Spain. These abstracts include a late breaker oral presentation that serves as the first academic presentation of an expanded dataset from the ARIEL3 clinical study.

ARIEL3 is a double-blind, placebo-controlled, phase 3 trial of rucaparib that enrolled 564 women with platinum-sensitive, high-grade ovarian, fallopian tube, or primary peritoneal cancer. Topline data announced in June 2017 demonstrate that ARIEL3 successfully achieved the primary endpoint of improved progression free survival by investigator review and blinded independent central review (BICR) in each of the three populations studied: tumor BRCA-mutant, HRD-positive and overall intent-to-treat populations. The safety of rucaparib observed in ARIEL3 was highly consistent with the U.S. treatment label for rucaparib. The September 8 ESMO presentation will provide comprehensive, detailed results of each ARIEL3 endpoint, along with a summary of safety data.

Additionally, two abstracts will provide an overview of the background and clinical trial design for the ongoing ARIEL4 study of rucaparib in ovarian cancer and the TRITON2 and TRITON3 studies of rucaparib in prostate cancer. These studies are evaluating rucaparib in germline and somatic BRCA-mutated, relapsed, high-grade ovarian cancer, and in metastatic castration-resistant prostate cancer associated with homologous recombination deficiency, respectively.

“We look forward to presenting the comprehensive dataset from our ARIEL3 clinical trial, which demonstrates rucaparib’s clinically meaningful benefit in the maintenance setting for women with platinum-sensitive, advanced ovarian cancer,” said Patrick J. Mahaffy, President and CEO of Clovis Oncology. “It has become increasingly clear that PARP inhibitors have a significant role to play in the current and future cancer-treatment paradigm, as monotherapy and potentially in combination with other therapeutic agents. The abstracts being presented at ESMO 2017 highlight our commitment to leveraging the very exciting potential of rucaparib in the fight against prostate and ovarian cancer, both devastating diseases for which we hope rucaparib may be able to offer new hope to patients and physicians.”

The three rucaparib abstracts accepted for presentation at the 2017 ESMO congress comprise:

Abstract LBA40– ARIEL3: A Phase 3, Randomised, Double-Blind Study of Rucaparib vs Placebo Following Response to Platinum-Based Chemotherapy for Recurrent Ovarian Carcinoma (OC)
Presenter: Professor Jonathan A. Ledermann, MD, University College London Cancer Institute and University College London Hospitals, UK
Session: Proffered paper session, Gynecological Cancers
Date/Time: Friday, September 8, 16:12-16:24 CEST
Location: Cordoba Auditorium
This abstract will also be featured in the ESMO press program from 08:15–09:00 CEST on Sunday, 10 September in Hall 10.

Abstract 988TIP – ARIEL4: An International, Randomised Phase 3 Study of the PARP Inhibitor Rucaparib vs Chemotherapy for the Treatment of BRCA-Mutated, Relapsed, High-Grade Ovarian Cancer
Presenter: Dr. Rebecca S. Kristeleit, MD, University College London Cancer Institute, UK

Session: Poster session
Date/Time: Saturday, September 9, 13:15-14:15 CEST
Location: Hall 8

Abstract 836TIP – The TRITON Clinical Trial Program: Evaluation of the PARP Inhibitor Rucaparib in Patients (Pts) with Metastatic Castration-Resistant Prostate Cancer (mCRPC) Associated with Homologous Recombination Deficiency (HRD)
Presenter: Dr. Simon Chowdhury, MD, Guy's Hospital & Sarah Cannon Research Institute, UK
Session: Poster session
Date/Time: Sunday, September 10, 13:15-14:15 CEST
Location: Hall 8

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

Investor/Analyst Briefing and Webcast

Clovis Oncology, Inc. will webcast an investor and analyst briefing in Madrid on Saturday, September 9 at 6:00 PM CEST in conjunction with the ESMO annual meeting. At this briefing, Clovis Oncology management will review the rucaparib development program and data presented at ESMO and answer questions from investors and analysts. This event will be webcast live and archived for 30 days, and may be accessed from the Clovis Oncology Investor Events and Presentations webpage at www.clovisoncology.com. The presentation will begin at 6:00 PM CEST for those institutional investors and analysts attending this event in Madrid; please RSVP to meetings@clovisoncology.com to attend.

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. In December 2016, rucaparib became the first PARP inhibitor approved by the U.S. Food and Drug Administration (FDA) as monotherapy for treatment of patients with deleterious BRCA mutation (germline and/or somatic) associated advanced ovarian cancer who have been treated with two or more prior chemotherapies. During the fourth quarter of 2016, the Marketing Authorization Application (MAA) submission in Europe for rucaparib in the same ovarian cancer treatment indication was submitted and accepted for review. By the end of October 2017, Clovis Oncology intends to submit a supplemental New Drug Application (sNDA) in the U.S. for a second line or later maintenance treatment indication in ovarian cancer based on the ARIEL3 data, and in early 2018, plans to file an MAA in Europe for the maintenance treatment indication upon receipt of a potential approval for the treatment indication. Studies open for enrollment or under consideration include ovarian, prostate, breast, pancreatic, gastroesophageal, bladder, lung and urothelial cancers. Clovis is also developing rucaparib in patients with mutant BRCA tumors and other DNA repair deficiencies beyond BRCA – commonly referred to as homologous recombination deficiencies, or HRD. 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. Examples of forward-

looking statements contained in this press release include, among others, statements regarding our expectation of timing for submission of the sNDA for rucaparib to the FDA, our expectations for regulatory developments in the EU with respect to rucaparib and our future development plans. 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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