Rucaparib MAA for the Ovarian Cancer Treatment Indication Referred by CHMP to Scientific Advisory Group on Oncology for Review Expected in February 2018

December 19, 2017

- **Treatment indication remains under active review**
- **The Scientific Advisory Group advice will assist CHMP to reach a positive or negative opinion**
- **In January 2018, the Company plans to notify the EMA of its intent to submit a new MAA in Q2 2018 for the maintenance treatment indication in women with advanced ovarian cancer**
- **In the event of a positive CHMP opinion and corresponding EMA approval, the Company plans to file a variation to the MAA for the maintenance treatment indication based on that approval and would not proceed with the new MAA**
- **The variation to the treatment MAA would be a more streamlined process with a six-month review**

BOULDER, Colo.--(BUSINESS WIRE)--Dec. 19, 2017-- Clovis Oncology, Inc. (NASDAQ: CLVS) announced today that the European Union's (EU) European Medicines Agency (EMA) Committee for Medicinal Products for Human Use (CHMP) has requested that the Scientific Advisory Group (SAG) on Oncology provide an opinion on aspects of the ongoing Marketing Authorization Application (MAA) relating to a potential conditional approval for rucaparib. The exact date for the SAG meeting has not yet been set but we expect it to take place in early February 2018.

The SAG on Oncology is convened at the request of the EMA to provide independent recommendations on scientific or technical matters related to pediatric and adult clinical oncology and hematology, or on any other scientific issue relevant to the work of the Agency that relates to this area.

"We continue to have as our priority the submission and potential approval for the maintenance treatment indication in advanced ovarian cancer in the EU," said Patrick J. Mahaffy, President and CEO of Clovis Oncology. "We anticipate that initiating the process to submit a new MAA for maintenance next month is the quickest path to provide the potential benefit of rucaparib to more women in the EU with advanced disease. Of course, if we receive an approval for the treatment indication in the second quarter, and we file a variation to the treatment MAA, we anticipate the potential maintenance approval would be swifter."

The CHMP application for the treatment indication currently under review was submitted during the fourth quarter of 2016 and was based on objective response rate and duration of response results from two multicenter, single-arm, open-label clinical trials, Study 10 and ARIEL2, in women with advanced BRCA-mutant ovarian cancer who had progressed after two or more prior chemotherapies. All 106 patients received rucaparib orally 600 mg twice daily as monotherapy until disease progression or unacceptable toxicity. Objective response rate (ORR) and duration of response (DOR) were assessed by the investigator according to Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1. The most common Grade 3/4 adverse event was anemia.

Both the variation to the MAA or a new MAA submission will be based on data from the phase 3 ARIEL3 clinical trial, which found that rucaparib significantly improved progression-free survival in all ovarian cancer patient populations studied. ARIEL3 is a double-blind, placebo-controlled trial of rucaparib that enrolled 564 women with platinum-sensitive, high-grade ovarian, fallopian tube, or primary peritoneal cancer. The primary efficacy analysis evaluated three prospectively defined molecular sub-groups in a step-down manner: 1) BRCA mutant; 2) HRD-positive; and finally, 3) the intent-to-treat population, or all patients treated in ARIEL3. Both the variation to the MAA or the new MAA filing will be directed at the broader intent-to-treat or "all comers" population.

Clovis announced positive topline results from the ARIEL3 clinical trial in June 2017. The comprehensive dataset from the trial was presented at the 2017 European Society for Medical Oncology (ESMO) Annual Conference in Madrid, Spain,[i] and subsequently published in *The Lancet*.[ii]

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 2017, the US Food and Drug Administration (FDA) accepted the Company's supplemental New Drug Application (sNDA) for rucaparib for a second-line or later maintenance treatment indication in ovarian cancer based on the ARIEL3 data. The FDA granted Priority Review status to the application with a Prescription Drug User Fee Act (PDUFA) date of April 6, 2018. In December 2017, the CHMP referred the rucaparib MAA for the ovarian cancer treatment indication to the SAG on Oncology for review. The SAG meeting to discuss the rucaparib MAA is anticipated in February 2018. Studies open for enrollment or under consideration include ovarian, prostate, breast, gastroesophageal, pancreatic, lung and bladder 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. Examples of forward-looking statements contained in this press release include, among others, statements regarding our expectation of timing for EMA regulatory steps, European approval of rucaparib for the treatment indication and the filing, review and potential approval of an MAA, or variation to the treatment MAA for a second line or later maintenance indication for rucaparib. 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 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.

[i] Ledermann, J., MD. ARIEL3: A phase 3, randomised, double-blind study of rucaparib vs placebo following response to platinum-based chemotherapy for recurrent ovarian carcinoma (OC). Presented at 2017 European Society for Medical Oncology Congress in Spain, Madrid. 8 September 2017.
[ii] Coleman R, et al. Rucaparib maintenance treatment for recurrent ovarian carcinoma after response to platinum therapy (ARIEL3): a randomised, double-blind, placebo-controlled, phase 3 trial. *The Lancet*. 12 September 2017. http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(17)32440-6/fulltext

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