Clovis Announces Priority Review Designation for Rucaparib Supplemental New Drug Application

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- **Clovis seeks U.S. approval for rucaparib as maintenance therapy for women with recurrent ovarian cancer who are platinum sensitive, and in complete or partial response to platinum chemotherapy, with no requirement for diagnostic testing**
- **Priority review granted based on positive data from phase 3 ARIEL3 clinical trial in which rucaparib significantly improved PFS in all ovarian cancer patient populations studied**
- **FDA assigns PDUFA date of April 6, 2018**

BOULDER, Colo.--(BUSINESS WIRE)--Dec. 5, 2017-- Clovis Oncology (NASDAQ: CLVS) announced today that the U.S. Food and Drug Administration (FDA) has accepted the company's supplemental New Drug Application (sNDA) for rucaparib and granted priority review status to the application with a Prescription Drug User Fee Act (PDUFA) date of April 6, 2018. In October, Clovis completed its sNDA submission for rucaparib as maintenance treatment in patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are platinum sensitive, and in a complete or partial response to platinum-based chemotherapy. The Company is seeking approval for use of rucaparib for this indication regardless of a patient's BRCA mutation status.

"We are pleased that we continue to make significant progress toward our goal of delivering rucaparib to a much broader population of women with advanced ovarian cancer," said Patrick J. Mahaffy, President and CEO of Clovis Oncology. "We are particularly encouraged by the FDA's decision to grant priority review to the application, which may allow us to make rucaparib available to these women in a more expeditious manner."

A priority review designation is granted to proposed medicines that the FDA has determined have the potential, if approved, to offer a significant improvement in the safety or effectiveness of the treatment, prevention or diagnosis of a serious condition. Priority designation shortens the review period from the standard ten months to six months from the acceptance of the NDA.

The rucaparib sNDA was submitted to the FDA in October 2017 and is based on data from the phase 3 ARIEL3 clinical trial. 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.

Clovis announced positive topline results from the ARIEL3 clinical trial in June 2017. Additional data from the trial were presented at the 2017 European Society for Medical Oncology (ESMO) Annual Conference in Madrid, Spain,[1] and subsequently published in The Lancet.[2]

Clovis intends to file a variation to the Marketing Authorization Application (MAA) in Europe in early 2018 for the maintenance indication, contingent on a potential approval in Europe for the ovarian cancer treatment indication.

About the ARIEL3 Clinical Trial

The ARIEL3 pivotal study of rucaparib is a confirmatory 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 complete or partial response to platinum-based chemotherapy. The study enrolled 564 patients with high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer. To be eligible for the study, participants had to have received at least two prior platinum-based treatment regimens, been sensitive to the penultimate platinum regimen, and achieved a complete or partial response to their most recent platinum-based regimen. There were no genomic selection criteria for this study. Trial participants were

randomized 2:1 to receive 600 milligrams of rucaparib twice daily (BID) or placebo.

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. During the fourth quarter of 2016, the Marketing Authorization Application (MAA) submission in Europe for rucaparib in an ovarian cancer treatment indication was submitted and accepted for review. A CHMP opinion is expected in late 2017. In October 2017, Clovis Oncology submitted 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. In early 2018, Clovis plans to file a variation to the MAA in Europe for the maintenance treatment indication contingent on a potential approval for the ovarian cancer treatment indication. Studies open for enrollment or under consideration include ovarian, prostate, breast, gastroesophageal, pancreatic, lung and bladder cancers. Clovis holds worldwide rights for rucaparib.

About Rubraca® (rucaparib)

Rubraca is a PARP inhibitor indicated in the U.S. as monotherapy for the treatment of patients with deleterious BRCA mutation (germline and/or somatic) associated advanced ovarian cancer, who have been treated with two or more chemotherapies, and selected for therapy based on an FDA-approved companion diagnostic for Rubraca. The indication for Rubraca is approved under the FDA's accelerated approval program based on objective response rate and duration of response, and is based on results from two multicenter, single-arm, open-label clinical trials. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. Please visit rubraca.com for more information.

About Ovarian Cancer

According to the American Cancer Society, more than 22,400 women will be diagnosed with ovarian cancer in the U.S. in 2017. There are often no clearly identifiable initial symptoms, and in an estimated 80 to 85 percent of ovarian cancer cases, the cancer has spread to other parts of the body before a person is diagnosed and can be treated. Ovarian cancer ranks fifth in cancer deaths and causes more deaths than any other cancer of the female reproductive system.

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 review and approval of the sNDA and submission, review and approval of the MAA 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 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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[1] 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.

[2] 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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