Clovis Oncology Receives Positive Trend Vote from CHMP in European Regulatory Review for Rucaparib Ovarian Cancer Treatment Indication

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- *The CHMP has communicated a positive trend vote for the rucaparib MAA under review for the treatment of women with advanced BRCA-mutant ovarian cancer and expects to vote on the treatment indication at their scheduled meeting in March 2018*
- *Pending a positive recommendation by CHMP, final approval by the European Commission would follow in Q2 2018*

BOULDER, Colo.--(BUSINESS WIRE)--Feb. 21, 2018-- Clovis Oncology, Inc. (NASDAQ: CLVS) announced today an update to the ongoing regulatory review for the Marketing Authorization Application (MAA) for rucaparib tablets as monotherapy for the treatment of a limited population of advanced ovarian cancer patients with deleterious BRCA mutation (germline and/or somatic). The indication under consideration by the Committee for Medicinal Products for Human Use (CHMP) focuses on a subset of platinum-sensitive disease where there is particular unmet medical need.

Following a Scientific Advisory Group (SAG) - Oncology last week and an oral explanation this week, the European Union's (EU) European Medicines Agency (EMA) CHMP has communicated a positive trend vote for the rucaparib MAA and their intention to hold a final vote on the treatment indication at their March meeting (March 19-22, 2018).

"We are pleased with this positive trend vote and the potential for a formal positive vote on the later-line treatment indication next month, especially for a patient population with a significant unmet clinical need," said Patrick J. Mahaffy, President and CEO of Clovis Oncology. "This potential approval also paves the way to a rapid review and potential CHMP vote for the maintenance indication by year-end in an earlier-line and all-comers population for women with advanced ovarian cancer."

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. 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.

Pending an approval for the treatment indication, Clovis plans to submit a variation to the MA 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 (BRCAmut+); 2) HRD-positive (HRD+) inclusive of BRCA-mutant; and finally, 3) the intent-to-treat population, or all patients treated in ARIEL3. The variation to the MA 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]

In the event of a negative vote next month by the CHMP, Clovis is prepared to submit a new MAA for the maintenance indication.

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 U.S. 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. Studies open for enrollment or under consideration include ovarian, prostate, breast, gastroesophageal, pancreatic, lung and bladder cancers. Clovis holds worldwide rights for rucaparib. Rucaparib is an unlicensed medical product in the EU.

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 and potential outcomes of European review and approval of rucaparib for the treatment indication and the filing, review and approval of an MAA or variation to an MA 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 EMA or other regulatory authorities regarding whether to approve drug applications that may be filed, the outcome of the formal CHMP vote, the timing of the regulatory review process or additional requirements for approval as well as their decisions that may affect drug labeling, pricing and reimbursement. 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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[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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Clovis Investor Contacts:
Anna Sussman, 303-625-5022
asussman@clovisoncology.com
or
Breanna Burkart, 303-625-5023

bburkart@clovisoncology.com
or
Clovis Media Contacts:
US
Lisa Guiterman, 301-217-9353
clovismedia@sambrown.com
or
Christy Curran, 615-414-8668
clovismedia@sambrown.com
or
EU
Ann Hughes, +44 (0) 7956 700 790
Ann.Hughes@publicisresolute.com