



CHMP Grants Positive Opinion for Clovis Oncology's Rubraca® (rucaparib) Tablets

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- **Rubraca offers a new option for women with advanced BRCA mutant ovarian cancer with platinum-sensitive, relapsed or progressive disease, who are unable to tolerate further platinum based chemotherapy**
- **First PARP inhibitor recommended for treatment indication in the EU**
- **European Commission (EC) formal approval is anticipated Q2 2018**
- **Once approved by the EC, Clovis plans to file a variation to the Marketing Authorization (MA) in Europe for Rubraca in the maintenance treatment setting**

BOULDER, Colo.--(BUSINESS WIRE)--Mar. 23, 2018-- Clovis Oncology, Inc. (NASDAQ: CLVS) today announced that the European Union's (EU) European Medicines Agency (EMA) Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion recommending the granting of a conditional marketing authorization for Rubraca as monotherapy treatment of adult patients with platinum sensitive, relapsed or progressive, BRCA mutated (germline and/or somatic), high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have been treated with two or more prior lines of platinum based chemotherapy, and who are unable to tolerate further platinum based chemotherapy.

The European Marketing Authorization application for the treatment indication 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.

"The recommendation to approve Rubraca as monotherapy is welcome news, as once approved it will offer a new treatment option for women with advanced, recurrent ovarian cancer who have BRCA mutant platinum sensitive disease and are unsuitable for platinum based chemotherapy. In this analysis, we observed many women benefiting from extended progression-free survival with acceptable tolerability," said Dr. Rebecca Kristeleit, Clinical Senior Lecturer and Consultant Medical Oncologist, University College London/University College London Hospitals UK. "These are really important data demonstrating meaningful efficacy and a new non-chemotherapy treatment option for this group of patients who have already been exposed to a number of chemotherapy regimens."

Ovarian cancer is the sixth deadliest cancer amongst women in Europe, where more than 65,000 women are diagnosed annually.ⁱ Ovarian cancer is challenging to treat, and most women will relapse after surgery and chemotherapy. The 80 to 85 percent of women diagnosed in the later stages of the disease (III and IV) have particularly poor outcomes.ⁱⁱ Approximately one in four women with ovarian cancer have a germline or somatic BRCA mutation,ⁱⁱⁱ and new treatment options are needed to treat unique patient populations.

"We are extremely pleased to have received a positive recommendation for approval for Rubraca in an ovarian cancer treatment indication, and we look forward to receiving the formal approval from the European Commission in second quarter 2018," said Patrick J. Mahaffy, President and CEO of Clovis Oncology. "This is great news for women living with this difficult disease who often have limited options available. In addition, this opinion from CHMP paves the way for the review of Rubraca in the ovarian cancer maintenance indication, based on the ARIEL3 data. We intend to file a variation to the Marketing Authorization (MA) in June, with a potential recommendation for approval in the broader maintenance indication by the end of 2018."

Pending approval for the treatment indication, Clovis plans to submit the 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 study achieved its primary endpoint of improved PFS by investigator review in each of three populations. The variation to the MA will be directed at the broader intent-to-treat or "all comers" population.

About Rubraca® (rucaparib)

Rubraca is an oral, small molecule inhibitor of PARP1, PARP2 and PARP3 being developed in ovarian cancer as well as several additional solid tumor indications. Studies open for enrollment or under consideration include ovarian, prostate, breast, gastroesophageal, pancreatic, lung and bladder cancers. Clovis holds worldwide rights for Rubraca.

In the United States, Rubraca is approved on an accelerated basis 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. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. In December 2017, the U.S. Food and Drug Administration (FDA) accepted the Company's supplemental New Drug Application (sNDA) for Rubraca 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.

Rubraca is an unlicensed medical product outside of the U.S.

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 European Commission approval of rucaparib for the treatment indication and the filing of a variation to the MA for a 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.

ⁱWorld Health Organization. Globocan 2012: estimated cancer incidence, mortality and prevalence worldwide in 2012. Accessed 23 February 2018.

ⁱⁱAmerican Cancer Society. Survival rates for ovarian cancer, by stage. <https://www.cancer.org/cancer/ovarian-cancer/detection-diagnosis-staging/survival-rates.html>

ⁱⁱⁱ Pennington KP, Walsh T, Harrell MI, et al. Germline and somatic mutations in homologous recombination genes predict platinum response and survival in ovarian, fallopian tube, and peritoneal carcinomas. *Clin Cancer Res.* 2014;20(3):764–775.

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