Clovis Oncology Announces European Commission Authorization of Rubraca® (rucaparib) for Women with Recurrent Ovarian Cancer

- ***First PARP inhibitor licensed for ovarian treatment indication in the EU***
- ***New option for women with recurrent BRCA mutant ovarian cancer with platinum-sensitive, relapsed or progressive disease, who are unable to tolerate further platinum-based chemotherapy***

BOULDER, Colo. – (BUSINESS WIRE) – May 29, 2018-- Clovis Oncology, Inc. (NASDAQ: CLVS) today announced that the European Commission (EC) has authorized Rubraca (rucaparib) 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. Certain confirmatory post-marketing commitments are required as part of this conditional authorization.

For the full European approved prescribing information, please refer to the Rubraca (rucaparib) Summary of Product Characteristics on the European Medicines Agency website.

"Rucaparib provides a unique opportunity within Europe for women with BRCA mutated ovarian cancer, for whom platinum chemotherapy isn't an option, to receive an oral non-chemotherapy treatment," said Dr. Rebecca Kristeleit, Clinical Senior Lecturer and Consultant Medical Oncologist, University College London, U.K. "In this group of patients with limited treatment options, rucaparib provides a much-needed oral targeted therapy for these women."

The project that led to rucaparib's discovery was among the first of the Newcastle Cancer Drug Discovery Group that started at Newcastle University, involving the Northern Institute for Cancer Research and a team of Cancer Research U.K.-funded scientists. Rucaparib went into phase 1 trials in 2003, with Ruth Plummer, Clinical Professor of Experimental Cancer Medicine at Newcastle University, leading the administration of rucaparib to the first patient in the world to be treated with the drug and the first ever cancer patient to be treated by a PARP inhibitor.

"Ovarian cancer is one of the most difficult cancers to detect and for this reason most women who develop the disease are often diagnosed in the advanced stages, leaving them with few viable treatment options," said Ruth Plummer, Clinical Professor of Experimental Medicine at the Northern Institute for Cancer Research, Newcastle University. "We are delighted that the culmination of many years of research from the team here in Newcastle has resulted in a new treatment option for women in the EU."

"We are pleased to receive this important authorization, as new options for women with recurrent ovarian cancer are needed," said Patrick J. Mahaffy, CEO and President of Clovis Oncology. "Importantly, the granting of the license means we are now able to submit a

variation to the Marketing Authorization for rucaparib to include the maintenance treatment setting based on ARIEL3 data, where we may soon be able to offer a new option to a larger population of women with recurrent ovarian cancer."

The EC approval was based on data from two multicenter, single-arm, open-label clinical trials, Study 10 (NCT01482715) and ARIEL2 (NCT01891344), in women with advanced BRCA-mutant ovarian cancer who had progressed after two or more prior chemotherapies. All patients received Rubraca orally 600 mg twice daily as monotherapy. Treatment continued until disease progression or unacceptable toxicity. The primary efficacy outcome measure of both studies was objective response rate (ORR) as assessed by the investigator according to Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1.

Based on investigator assessment of response, rucaparib showed an objective response rate (ORR) of 54.7% (95% CI [44.8, 64.4], in the primary efficacy population (N=106) and 64.6% (95% CI [53.0, 75.0], in the platinum sensitive population (N=79). The independent radiology review response rate reported was consistent with the investigator assessed response rate reported.

Adverse reactions occurring in ≥ 20% of patients receiving rucaparib were fatigue/asthenia, nausea, creatinine elevations, ALT elevations, AST elevations, vomiting, anemia, decreased appetite, dysgeusia, diarrhea, and thrombocytopenia. The majority of adverse reactions were mild to moderate (Grade 1 or 2). The ≥ Grade 3 adverse reactions occurring in > 5% of patients were anemia (23%), increased ALT (10%), fatigue/asthenia (9%), neutropenia (9%), and thrombocytopenia (5%). The only serious adverse reaction occurring in >2% of patients was anemia (5%). Adverse reactions that most commonly led to dose reduction or interruption were anemia (22%), fatigue/asthenia (19%), and nausea (15%). Adverse reactions leading to permanent discontinuation occurred in 8% of patients, with asthenia/fatigue being the most frequent adverse reaction leading to permanent discontinuation.

About Rubraca® (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. Studies open for enrollment or under consideration include ovarian, prostate, breast, gastroesophageal, pancreatic, lung and bladder cancers. Clovis holds worldwide rights for rucaparib.

In the United States (U.S.), rucaparib is approved for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy. Rucaparib is also approved in the United States for the treatment of adult patients with deleterious BRCA mutation (germline and/or somatic) associated epithelial ovarian, fallopian tube, or primary peritoneal

cancer who have been treated with two or more chemotherapies, and selected for therapy based on an FDA- approved companion diagnostic for rucaparib.

Rucaparib is an unlicensed medical product outside of the U.S. and 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 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 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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