Clovis Oncology's Rucaparib ARIEL3 Study Data Published in The Lancet

September 13, 2017

- **ARIEL3 evaluated rucaparib as maintenance treatment among women with advanced ovarian cancer**
- **Study successfully achieved primary, key secondary and exploratory endpoints**
- **Company plans to submit a supplemental New Drug Application (sNDA) in the U.S. for maintenance treatment indication in ovarian cancer by the end of October 2017**

BOULDER, Colo.--(BUSINESS WIRE)--Sep. 13, 2017-- Clovis Oncology, Inc. (NASDAQ: CLVS) announced that comprehensive data from the Phase 3 ARIEL3 study of rucaparib for maintenance treatment of advanced ovarian cancer were published online today in *The Lancet*. The ARIEL3 study successfully achieved its primary and key secondary endpoints - improved progression-free survival (PFS) by both investigator review and blinded independent central review (BICR), respectively - in each of the three populations studied, as well as its exploratory endpoints.

ARIEL3 is a double-blind, placebo-controlled, phase 3 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) tumor BRCA mutant (tBRCAmut) patients, inclusive of germline and somatic mutations of BRCA (n=196); 2) HRD patients, including BRCA-mutant patients and BRCA wild-type with high loss of heterozygosity, or LOH-high patients (n=354), and, finally, 3) the intent-to-treat population, or all patients treated in ARIEL3 (n=564). The study achieved its primary endpoint of improved PFS by investigator review in each of three populations. PFS was also improved in the rucaparib group compared with placebo by BICR, a key secondary endpoint, in all three populations. In addition, rucaparib improved objective response rate vs placebo among evaluable trial participants in all three study populations.

"The publication of the ARIEL3 data in this prestigious, peer-review journal reinforces the importance of identifying new therapies that provide meaningful clinical benefit to women with advanced ovarian cancer, and speaks to the high quality of the study design and the data we were able to deliver," said Patrick J. Mahaffy, President and CEO of Clovis Oncology. "We extend our sincere thanks to the study investigators and authors, as well as the many patients, who supported and participated in ARIEL3."

"The extension in PFS in the ARIEL3 intent-to-treat population demonstrates that patients with platinum-sensitive ovarian carcinoma can derive robust clinical benefit from rucaparib maintenance treatment, regardless of their mutational status," said Robert L. Coleman, M.D., professor and vice chair, clinical research, in the Department of Gynecologic Oncology and Reproductive Medicine at The University of Texas MD Anderson Cancer Center and the U.S. principal investigator for the ARIEL3 study. "Additionally, the ARIEL3 study was intentionally designed to deliver multiple, key insights that will help inform treatment decisions and management of advanced ovarian cancer patients going forward."

According to the paper published today, treatment emergent adverse events (TEAEs) in the ARIEL3 rucaparib group were generally managed with dose modifications and not associated with increased mortality or morbidity compared with the placebo group. Safety data from ARIEL3 demonstrate consistency with prior rucaparib studies.

In December 2016, Rubraca® became the first PARP inhibitor approved by the U.S. Food and Drug Administration (FDA) as monotherapy for treatment of patients with deleterious BRCA mutation (germline and/or somatic) associated advanced ovarian cancer who have been treated with two or more prior chemotherapies. During the fourth quarter of 2016, a Marketing Authorization Application (MAA) was submitted and accepted in Europe for Rubraca in the same ovarian cancer-treatment indication.

Based on the ARIEL3 findings, Clovis Oncology plans to submit a supplemental New Drug Application (sNDA) to the U.S. FDA for a second line or later maintenance treatment indication in ovarian cancer by the end of October 2017. In early 2018, the Company plans to file an MAA in Europe for the maintenance treatment indication upon receipt of a potential approval for the 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. In December 2016, rucaparib became the first PARP inhibitor approved by the U.S. Food and Drug Administration (FDA) as monotherapy for treatment of patients with deleterious BRCA mutation (germline and/or somatic) associated advanced ovarian cancer who have been treated with two or more prior chemotherapies. Studies open for enrollment or under consideration include ovarian, prostate, breast, pancreatic, gastroesophageal, bladder, lung and urothelial cancers. Clovis is also developing rucaparib in patients with mutant BRCA tumors and other DNA repair deficiencies beyond BRCA – commonly referred to as homologous recombination deficiencies, or HRD. Clovis holds worldwide rights for rucaparib.

About Ovarian Cancer

Ovarian cancer is the sixth deadliest cancer amongst women in Europe,[i] where more than 65,000 women are diagnosed annually.[ii] 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.[iii] Approximately one in four women with ovarian cancer have a germline or somatic BRCA mutation,[iv] and new treatment options are needed to treat unique patient populations.

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 submission of the sNDA for rucaparib, European approval of rucaparib for the treatment indication and the filing of an 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 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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[i] World Health Organization. Globocan 2012: estimated cancer incidence, mortality and prevalence worldwide in 2012. http://globocan.iarc.fr/Pages/fact_sheets_population.aspx

[ii] Ferlay J, et al. Eur J Cancer 2013;49:1374–1403

[iii] American Cancer Society. Survival rates for ovarian cancer, by stage. https://www.cancer.org/cancer/ovarian-cancer/detection-diagnosis-staging/survival-rates.html

[iv] 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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Source: Clovis Oncology, Inc.

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