Clovis Oncology's Rucaparib Significantly Improved Progression-Free Survival in All Ovarian Cancer Patient Populations Studied in Phase 3 ARIEL3 Maintenance Treatment Trial

- **The ARIEL3 study successfully achieved its primary endpoint of improved PFS by investigator review in all three primary efficacy analyses: tumor BRCA-mutant, HRD-positive and overall intent-to-treat populations**
- **The ARIEL3 study successfully achieved the key secondary endpoint of improved PFS by blinded, independent central review (BICR) in each of the tumor BRCA-mutant, HRD-positive and overall intent-to-treat populations**
- **The exploratory PFS endpoints were achieved by both investigator and independent review in the HRD-positive and HRD-negative subgroups of patients without a BRCA mutation**
- **ARIEL3 patients with residual disease at study entry who were treated with rucaparib showed further reduction in tumor burden, including complete responses**
- **The safety of rucaparib observed in ARIEL3 was highly consistent with the U.S. treatment label for Rubraca®**
- **The Company plans to submit a supplemental NDA within the next four months**

BOULDER, Colo. (BUSINESS WIRE) June 19, 2017 -- Clovis Oncology, Inc. (NASDAQ: CLVS) today announced topline data from the confirmatory phase 3 ARIEL3 trial of rucaparib, which successfully achieved the primary endpoint of improved progression-free survival (PFS) by investigator review in each of the three populations studied. PFS was also improved in the rucaparib group compared with placebo by blinded independent central review (BICR), a key secondary endpoint. Based on these findings, the Company plans to submit a supplemental New Drug Application (sNDA) within the next four months for a second-line and later maintenance treatment indication for all women with platinum-sensitive ovarian cancer who have responded to their most recent platinum therapy.

"We are very pleased with these positive ARIEL3 topline results that strongly demonstrate the potential of rucaparib to help women with platinum-sensitive, advanced ovarian cancer," said Patrick J. Mahaffy, President and CEO of Clovis Oncology. "These results reinforce the potentially foundational role of rucaparib in the management of advanced ovarian cancer, as demonstrated by both investigator review and the blinded independent central review. Most importantly, we are grateful to the patients, caregivers and investigators who participated in this study. We look forward to sharing these data in greater detail at a medical meeting later this year and submitting our sNDA as rapidly as possible, with the ultimate goal of making rucaparib available to more women battling ovarian cancer."

"Based on these encouraging data, it is clear that rucaparib demonstrates a clinically meaningful impact in delaying disease recurrence in women in this trial with advanced ovarian cancer," 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 in Houston and the U.S. Principal investigator for the ARIEL3 study. "The PFS and safety results achieved in this study are particularly promising, because they suggest

women are able to stay on rucaparib for a prolonged period of time while gaining benefit. It is also clinically significant that rucaparib not only sustained the most recent response to platinum, but in some patients also enhanced that response, including the elimination of residual tumor."

"I first dosed a patient with rucaparib over five years ago, and these robust and exciting data are consistent with my experience," said Professor Jonathan Ledermann, Professor of Medical Oncology, Director, Cancer Research UK and UCL Cancer Trials Centre, UCL Cancer Institute, and European and ROW Principal Investigator for the ARIEL3 study. "These results show that rucaparib has the potential to provide an enduring and important clinical benefit in women with advanced ovarian cancer, irrespective of their tumor genetics. This is a very important step forward for women with advanced ovarian cancer."

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; 2) HRD-positive patients, including BRCA-mutant patients and BRCA wild-type with high loss of heterozygosity, or LOH-high patients, and, finally, 3) the intent-to-treat population, or all patients treated in ARIEL3.

Following is a table and a summary of the primary efficacy analyses and selected exploratory PFS endpoints per Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1 by each of investigator review, which was the primary analysis of ARIEL3, and independent review (BICR), a key secondary endpoint of the study.

Summary of Primary Efficacy Analyses and Selected Exploratory Endpoints for ARIEL3

ARIEL3 Analysis Population	PFS by Investigator Review *(Primary Endpoint)*		PFS by Blinded Independent Central Review *(Key Secondary Endpoint)*	
Primary Analyses				
	Hazard Ratio	**Median PFS (months) Rucaparib vs. Placebo**	**Hazard Ratio**	**Median PFS (months) Rucaparib vs. Placebo**
tBRCAmut (n=196)	0.23; p<0.0001	16.6 vs. 5.4	0.20; p<0.0001	26.8 vs. 5.4
HRD-positive (n=354)	0.32; p<0.0001	13.6 vs. 5.4	0.34; p<0.0001	22.9 vs. 5.5
Intent-to-Treat (n=564)	0.36; p<0.0001	10.8 vs. 5.4	0.35; p<0.0001	13.7 vs. 5.4
Exploratory Analyses				
BRCA^{wt} / HRD-positive (n=158)	0.44; p<0.0001	9.7 vs. 5.4	0.55; p=0.0135	11.1 vs. 5.6
BRCA^{wt} / HRD-negative (n=161)	0.58; p=0.0049	6.7 vs. 5.4	0.47; p=0.0003	8.2 vs. 5.3

PFS: progression-free survival; tBRCAmut: tumor BRCA mutant; HRD: homologous recombination deficiency; BRCAwt: BRCA wild type

"Ovarian cancer is the deadliest gynecologic cancer and until very recently, there were limited treatment options for advanced disease," said David Barley, Chief Executive Officer of the National Ovarian Cancer Coalition. "The potential for targeted therapies that can meaningfully delay recurrence for a large percentage of women with this disease is significant, and we are encouraged by these results from ARIEL3."

Significant Improvement in PFS in the tBRCAmut Patient Population
The most robust clinical outcomes were observed among ARIEL3 patients with a germline or somatic BRCA mutation (n=196). By investigator review, the rucaparib arm successfully achieved statistical significance over the placebo arm for the primary endpoint of PFS with a hazard ratio of 0.23 ($p<0.0001$). The median PFS for the tBRCAmut patients treated with rucaparib was 16.6 months vs. 5.4 months among those who received placebo.

By independent review (BICR), the rucaparib arm improved PFS over the placebo arm with a hazard ratio of 0.20 ($p<0.0001$). The median PFS for the tBRCAmut patients treated with rucaparib was 26.8 months vs. 5.4 months among those who received placebo.

Results were consistent for the germline BRCA (n=130) and somatic BRCA (n=56) populations.

Significant Improvement in PFS in the HRD positive Patient Population
This population included patients with a germline or somatic mutation of BRCA, as well as those whose tumors were BRCA wild type (BRCAwt) but determined to be HRD positive as defined by a Foundation Medicine assay (n=354). By investigator review, the rucaparib arm successfully achieved statistical significance over the placebo arm for the primary endpoint of PFS with a hazard ratio of 0.32 ($p<0.0001$). The median PFS for the HRD-positive patients treated with rucaparib was 13.6 months vs. 5.4 months among those who received placebo.

By independent review (BICR), the rucaparib arm improved PFS over the placebo arm with a hazard ratio of 0.34 ($p<0.0001$). The median PFS for the HRD-positive patients treated with rucaparib was 22.9 months vs. 5.5 months among those who received placebo.

Significant Improvement in PFS in All Patients Studied
Rucaparib also showed statistical significance in all 564 patients enrolled in the study. By investigator review, the rucaparib arm successfully achieved statistical significance over the placebo arm for the primary endpoint of PFS with a hazard ratio of 0.36 ($p<0.0001$). The median PFS for all patients treated with rucaparib was 10.8 months vs. 5.4 months for those who received placebo.

By independent review (BICR), the rucaparib arm improved PFS over the placebo arm with a hazard ratio of 0.35 ($p<0.0001$). The median PFS for all patients enrolled in ARIEL3 and treated with rucaparib was 13.7 months vs. 5.4 months for those who received placebo.

Exploratory PFS Endpoint Achieved in BRCAwt/HRD-positive Subgroup
The exploratory PFS endpoint was achieved in the 158 patients identified as BRCAwt HRD positive. By investigator review, the rucaparib arm successfully achieved its endpoint over the placebo arm for the primary endpoint of PFS with a hazard ratio of 0.44 ($p<0.0001$). The median PFS for these patients treated with rucaparib was 9.7 months vs. 5.4 months for those who received placebo.

By independent review (BICR), the rucaparib arm improved PFS over the placebo arm with a hazard ratio of 0.55 (p=0.014). The median PFS for these patients treated with rucaparib was 11.1 months vs. 5.6 months for those who received placebo.

Exploratory PFS Endpoint Achieved in BRCAwt/HRD-negative Subgroup
The exploratory PFS endpoint was achieved in the 161 patients identified as BRCAwt and HRD-negative. By investigator review, the rucaparib arm successfully achieved its endpoint over the placebo arm for the primary endpoint of PFS with a hazard ratio of 0.58 (p=0.0049). The median PFS for these patients treated with rucaparib was 6.7 months vs. 5.4 months for those who received placebo.

By independent review (BICR), the rucaparib arm improved PFS over the placebo arm with a hazard ratio of 0.47 (p=.0003). The median PFS for these patients treated with rucaparib was 8.2 months vs. 5.3 months for those who received placebo.

Exploratory Endpoint of Response Rate
Enrollment in ARIEL3 included one-third of patients who had achieved a complete response to their prior platinum-based therapy, and two-thirds of patients who had achieved a partial response to their prior platinum-based therapy. Of those with a partial response, 37% had measurable disease at the time of enrollment and were therefore evaluable for response. The confirmed overall response rate by investigator-assessed RECISTv1.1 in the tBRCAmut group treated with rucaparib was 38% (15/40), of these, 18% (7/40) were complete responses. This compared with 9% (2/23) in the placebo group (p=0.0055). No complete responses were seen in the tBRCAmut placebo group. RECIST responses were also observed in BRCA wild type HRD positive and BRCA wild type HRD negative subgroups.

RECIST responses were not assessed by independent blinded review.

Summary of ARIEL3 Safety
The most common (≥5%) treatment-emergent grade 3/4 adverse events (TEAEs) among all patients treated with rucaparib in the ARIEL3 study were anemia/decreased hemoglobin (19%), ALT/AST increase (11%), asthenia/fatigue (7%), neutropenia (7%), and thrombocytopenia (5%).The discontinuation rate for TEAEs was 14% for rucaparib-treated patients and 2.6% for the placebo arm. The rate of treatment-emergent myelodysplastic syndrome (MDS)/acute myeloid leukemia (AML) in the rucaparib arm was <1% (3/372), and no patients on the placebo arm experienced treatment-emergent MDS/AML.

Clovis Oncology plans to provide an expanded description of the ARIEL3 results in a scientific session at a medical meeting later this year.

Rucaparib and Rubraca® Regulatory Status
In December 2016, Rubraca (rucaparib) tablets became the first poly ADP-ribose polymerase (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. The Company intends to submit a sNDA for a second line or later maintenance treatment indication

in ovarian cancer based on the ARIEL3 data within the next four months, and the Company also plans to file a Marketing Authorization Application (MAA) in Europe for the maintenance indication.

Conference Call Details
Clovis will hold a conference call to discuss the ARIEL3 results this morning, June 19, at 8:30am ET. The conference call will be simultaneously webcast on the Company's web site at www.clovisoncology.com, and archived for future review. Dial-in numbers for the conference call are as follows: US participants 866.489.9022, International participants 678.509.7575, conference ID: **42436102**.

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. The MAA submission in Europe for an ovarian cancer treatment indication was submitted and accepted for review during the fourth quarter of 2016. The company plans to submit data from the completed ARIEL3 trial to the FDA for an sNDA for a second line and later maintenance treatment indication. Rucaparib is also being developed 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
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% 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. One in four women with ovarian cancer have a germline or somatic BRCA mutation, 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 and to present the ARIEL3 data set at an upcoming medical meeting. 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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