Clovis Oncology Announces Second Quarter 2017 Operating Results

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- *Strong second quarter of launch for Rubraca® (rucaparib) in U.S. with $14.6M reported in net sales*
- *Positive topline data from the ARIEL3 study reported on June 19, 2017; presentation of full dataset confirmed at European Society for Medical Oncology 2017 Congress in Madrid*
- *Clovis plans to submit a supplemental New Drug Application (sNDA) for a second-line and later maintenance treatment indication before the end of October*
- *Rucaparib E.U. Marketing Authorization Application under review; establishing E.U. organization to support a potential European launch*
- *Broad clinical collaboration with Bristol-Myers Squibb to evaluate Rubraca in combination with Opdivo® (nivolumab) in several late-stage clinical trials in multiple tumor types; studies are expected to begin before the end of 2017*

BOULDER, Colo.--(BUSINESS WIRE)--Aug. 2, 2017-- Clovis Oncology, Inc. (NASDAQ:CLVS) reported financial results for the quarter ended June 30, 2017, and provided an update on the Company's clinical development programs and regulatory outlook for the remainder of 2017.

"This is clearly an exciting time for our company, for PARP inhibitors generally, and for Rubraca specifically," said Patrick J. Mahaffy, President and CEO of Clovis Oncology. "We are actively preparing our supplemental New Drug Application for an all-comers population in the platinum-sensitive ovarian cancer second-line and later maintenance treatment setting based on the ARIEL3 data. We anticipate an opinion on our initial treatment indication in Europe by year-end 2017, and we are preparing our supplemental application in Europe in second-line maintenance treatment to be filed immediately upon receipt of a potential treatment approval, which is anticipated in early 2018. And finally, we are extremely enthusiastic about our clinical collaboration with Bristol-Myers Squibb to explore the combination of *Opdivo* and *Rubraca* in triple-negative breast, ovarian and prostate cancers, which could represent a potentially foundational therapy in these and other tumor types."

Second Quarter 2017 Financial Results

Following the approval and launch of Rubraca on December 19, 2016, Clovis reported net product revenue for Rubraca of $14.6 million for the second quarter of 2017, compared to net product revenue of $7.0 million in the first quarter of 2017 for a total of $21.6 million for the first six months of 2017.

Clovis had $671.5 million in cash, cash equivalents and available-for-sale securities as of June 30, 2017. Cash used in operating activities was $69.1 million for the second quarter of 2017 and $149.5 million for the first half of 2017, compared with $68.0 million and $151.7 million for the comparable periods of 2016. Clovis had approximately 45.2 million shares of common stock outstanding as of June 30, 2017. In January 2017, the Company raised net proceeds of $221.2 million through an offering of 5.75 million shares of common stock and in June 2017, the Company raised net proceeds of $324.9 million through an offering of 3.92 million shares of common stock.

Clovis reported a net loss for the second quarter of 2017 of $175.4 million, or a net loss of $3.88 per share, and $233.8 million, or a net loss of $5.24 per share for the first half of 2017. Net loss was $129.3 million, or a net loss of $3.37 per share for the second quarter of 2016, and $212.7 million, or a net loss of $5.54 per share for the first half of 2016. The net loss for the quarter and six months ended June 30, 2017 included a charge of $117.0 million related to a legal settlement. The net loss for the quarter and six months ended June 30, 2016 included a charge of $104.5 million for the impairment of an intangible asset, a gain of $25.5 million for a reduction in fair value of contingent purchase consideration and a $29.2 million non-cash tax benefit related to lucitanib product rights recorded in 2013 in connection with the Company's acquisition of Ethical Oncology Science S.p.A. The adjusted net loss excluding these items was $58.4 million or $1.29 per share for the second quarter and $116.8 million or $2.62 per share for the six months ended 2017 and $79.4 million or

$2.07 per share for the second quarter and $162.8 million or $4.24 per share for the six months ended 2016. Net loss for the second quarter of 2017 included share-based compensation expense of $10.7 million and $19.6 million for the first half of 2017, compared to $9.5 million and $20.5 million for the comparable periods of 2016.

Research and development expenses totaled $33.1 million for the second quarter of 2017 and $65.6 million for the first half of 2017, compared to $67.7 million and $142.3 million for the comparable periods in 2016. The decrease year over year is primarily due to lower spending on rucaparib and rociletinib development activities and selling, general and administrative expenses related to the commercialization of Rubraca, which had been classified as research and development prior to FDA approval.

Selling, general and administrative expenses totaled $36.1 million for the second quarter of 2017 and $65.4 million for the first half of 2017, compared to $9.6 million and $19.4 million for the comparable periods in 2016. The increase year over year is primarily due to selling, general and administrative expenses related to the commercialization of Rubraca, which had been classified as research and development prior to FDA approval.

New Clinical Collaboration with Bristol-Myers Squibb

Earlier in the week, Clovis and Bristol-Myers Squibb announced a broad clinical collaboration to evaluate the combination of Opdivo and rucaparib in Phase 2 and pivotal Phase 3 clinical trials in multiple tumor types. The pivotal Phase 3 trials will evaluate rucaparib in combination with Opdivo, rucaparib as monotherapy and Opdivo as monotherapy in first-line maintenance treatment for advanced ovarian and advanced triple-negative breast cancers. The Phase 2 trial will evaluate Opdivo in combination with rucaparib and other compounds in metastatic castrate-resistant prostate cancer (mCRPC). These trials are anticipated to begin by the end of 2017. The planned multi-arm clinical trials will be conducted in the U.S., Europe and possibly additional countries. Clovis will be the study sponsor and conducting party for the ovarian cancer study, and Bristol-Myers Squibb will be the study sponsor and conducting party for the breast and prostate cancer studies. Specific terms of the agreement were not disclosed.

ARIEL3 Topline Results

On June 19, Clovis 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.

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 Primary Analyses	**PFS by Investigator Review *(Primary Endpoint)***		**PFS by Blinded Independent Central Review *(Key Secondary Endpoint)***	
	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; $BRCA^{wt}$: BRCA wild type

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.

The ARIEL3 data has been accepted at the European Society for Medical Oncology 2017 Congress in Madrid this September.

Rucaparib Regulatory Update

Based on the ARIEL3 dataset, the Company plans to submit a supplemental New Drug Application (sNDA) by the end of October 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.

Clovis' Marketing Authorization Application (MAA) for rucaparib to the European Medicines Agency for a comparable ovarian cancer treatment indication that was submitted to the U.S. FDA is currently under review. Clovis anticipates an opinion from the Committee for Medicinal Products for Human Use (CHMP) in late 2017, and, pending a favorable opinion from CHMP, a potential approval would follow during the first quarter of 2018. Following a potential approval for the treatment indication, Clovis intends to submit a supplemental application for the second-line or later maintenance treatment indication, for which the Company anticipates a potential approval during the third quarter of 2018. Clovis

continues to establish its E.U. organization to support a potential launch of rucaparib.

Rucaparib Clinical Development

Clovis has a robust clinical development program underway in multiple tumor types, including both Clovis-sponsored and investigator-initiated trials. The following clinical studies are open for enrollment or are anticipated to open during 2017:

- The Clovis-sponsored ARIEL4 confirmatory study in the treatment setting is a Phase 3 multicenter, randomized study of rucaparib versus chemotherapy in relapsed ovarian cancer patients with BRCA mutations (inclusive of germline and/or somatic) who have failed two prior lines of therapy. The primary endpoint of the study is PFS. This study is currently enrolling patients.
- The Clovis-sponsored TRITON2 (**T**rial of **R**ucapar**i**b in Pros**t**ate Indicati**on**s) study in mCRPC, a Phase 2 single-arm study enrolling patients with BRCA mutations and ATM mutations (both inclusive of germline and somatic) or other deleterious mutations in other homologous recombination (HR) repair genes and all patients will have progressed after receiving one line of taxane-based chemotherapy and one or two lines of androgen-receptor (AR) targeted therapy. This study is currently enrolling patients.
- The Clovis-sponsored TRITON3 study, a Phase 3 comparative study in mCRPC enrolling BRCA mutant and ATM mutant (both inclusive of germline and somatic) patients who have progressed on AR-targeted therapy and who have not yet received chemotherapy in the castrate-resistant setting is also open for enrollment. TRITON3 will compare rucaparib to physician's choice of AR-targeted therapy or chemotherapy in these patients. This study is currently enrolling patients.
- A Clovis-sponsored Phase 3 study in advanced ovarian cancer in the first-line maintenance treatment setting evaluating rucaparib plus the cancer immunotherapy Opdivo (nivolumab; anti-PD1), rucaparib, Opdivo and placebo in newly-diagnosed patients who have completed platinum-based chemotherapy. This study, as part of a broad clinical collaboration with Bristol-Myers Squibb, is expected to begin before the end of 2017.
- The Phase 3 combination study of the cancer immunotherapy Opdivo plus rucaparib for the treatment of advanced triple-negative breast cancers (TNBC) associated with homologous recombination deficiency (HRD). This study is sponsored by Bristol-Myers Squibb and is expected to begin before the end of 2017.
- The Phase 2 combination study of the cancer immunotherapy Opdivo plus rucaparib for the treatment of mCRPC. This study, sponsored by Bristol-Myers Squibb, will be conducted as an arm of a larger Bristol-Myers Squibb-sponsored prostate cancer study. This study is expected to begin before the end of 2017.
- The Phase 1b combination study of the cancer immunotherapy Tecentriq (atezolizumab; anti-PDL1) and rucaparib for the treatment of gynecological cancers, with a focus on ovarian cancer. This study is sponsored by Roche and is currently enrolling patients.
- The cooperative group-sponsored MITO-25 study evaluating rucaparib and the anti-angiogenic therapy, bevacizumab, in combination as a first-line maintenance therapy for advanced ovarian cancer, which is expected to begin enrolling patients by year-end; and
- Additional investigator-initiated or cooperative group-initiated studies of rucaparib as single-agent or in combination therapy are underway or planned, including studies in ovarian, prostate, breast, gastroesophageal, pancreatic, lung, bladder and urothelial cancers.

Conference Call Details

Clovis will hold a conference call to discuss second quarter 2017 results on August 2, at 4:30pm 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: **58222782**.

About Rubraca® (rucaparib)

Rubraca is a PARP inhibitor indicated 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. The indication for Rubraca is approved under the FDA's accelerated approval program based on objective response rate and duration of response, and is based on results from two multicenter, single-arm, open-label clinical trials. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. Please visit rubraca.com for more information.

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. During the fourth quarter of 2016, the Marketing Authorization Application (MAA) submission in Europe for rucaparib in the same ovarian cancer treatment indication was submitted and accepted for review. In October 2017, Clovis Oncology intends to submit a supplemental New Drug Application (sNDA) in the U.S. for a second line or later maintenance treatment indication in ovarian cancer based on the ARIEL3 data, and in addition, plans to file an MAA in Europe for the maintenance treatment indication. Studies open for enrollment or under consideration include ovarian, prostate, breast, gastroesophageal, pancreatic, lung, bladder 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 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. 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 market potential of our approved drug, including the performance of our sales and marketing efforts and the success of competing drugs, the performance of our third-party manufacturers, our clinical development programs for our drug candidates, the corresponding development pathways of our companion diagnostics, the timing of availability of data from our clinical trials and the results, 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.

CLOVIS ONCOLOGY, INC
CONSOLIDATED FINANCIAL RESULTS
(Unaudited, in thousands, except per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Revenues:				
Product revenue, net	$ 14,620	$ -	$ 21,665	$ -
Operating expenses:				
Cost of sales - product	2,730	-	3,893	-
Cost of sales - intangible asset amortization	372	-	743	-
Research and development	33,108	67,729	65,555	142,337
Selling, general and administrative	36,149	9,552	65,373	19,379
Acquired in-process research and development	-	300	-	300
Impairment of intangible asset	-	104,517	-	104,517
Change in fair value of contingent purchase consideration	-	(25,452)	-	(24,936)
Total expenses	72,359	156,646	135,564	241,597
Operating loss	(57,739)	(156,646)	(113,899)	(241,597)
Other income (expense):				
Interest expense	(2,598)	(2,106)	(5,178)	(4,210)
Foreign currency gain (loss)	76	183	(83)	(368)
Legal settlement loss	(117,000)	-	(117,000)	-
Other income	594	196	946	221
Other income (expense), net	(118,928)	(1,727)	(121,315)	(4,357)
Loss before income taxes	(176,667)	(158,373)	(235,214)	(245,954)
Income tax benefit	1,281	29,059	1,365	33,240
Net loss	$ (175,386)	$ (129,314)	$ (233,849)	$ (212,714)
Basic and diluted net loss per common share	$ (3.88)	$ (3.37)	$ (5.24)	$ (5.54)
Basic and diluted weighted-average common shares outstanding	45,176	38,389	44,610	38,375

RECONCILIATION OF GAAP TO NON-GAAP NET LOSS AND NET LOSS PER SHARE

(Unaudited, in thousands, except per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
GAAP net loss	$ (175,386)	$ (129,314)	$ (233,849)	$ (212,714)

Adjustments:				
Legal settlement loss (1)	117,000	-	117,000	-
Impairment of intangible asset (2)		104,517		104,517
Change in fair value of contingent purchase consideration (3)		(25,452)		(25,452)
Income tax benefit (2)		(29,160)		(29,160)
Non-GAAP net loss	$ (58,386)	$ (79,409)	$ (116,849)	$ (162,809)
GAAP net loss per common share	$ (3.88)	$ (3.37)	$ (5.24)	$ (5.54)
Non-GAAP net loss per common share	$ (1.29)	$ (2.07)	$ (2.62)	$ (4.24)

The Company prepares its consolidated financial statements in accordance with U.S. GAAP. This press release also contains non-GAAP measurements of net loss and net loss per common share that the Company believes provide useful supplemental information relating to operating performance and trends and facilitates comparisons with other periods. These non-GAAP financial measures should be considered in addition to, but not as a substitute for, the information prepared in accordance with U.S. GAAP.

Explanation of adjustments:

(1) During the three months ended June 30, 2017, the Company recorded a $117.0 million legal settlement loss related to a stipulation and agreement of settlement entered into between the Clovis Defendants and the plaintiffs to the Consolidated Complaint.

(2) During the three months ended June 30, 2016, the Company recorded a $104.5 million non-cash impairment charge to the intangible asset related to the lucitanib product rights initially recorded in 2013 in connection with the acquisition of Ethical Oncology Science, S.p.A. (EOS). The Company also recorded a $29.2 million tax benefit associated with this charge. This adjustment removes the net of tax effect of this charge from our net loss.

(3) During the three months ended June 30, 2016, the Company recorded a $25.5 million non-cash credit to operating expenses to reflect the reduction in the fair value of the contingent purchase consideration liability, also associated with the Company's acquisition of EOS. This adjustment, which excludes the normal accretion of the liability, removes the effect of this expense credit from our net loss.

CONSOLIDATED BALANCE SHEET DATA

(Unaudited,in thousands)

	June 30, 2017	**December 31, 2016**
Cash and cash equivalents	$ 491,786	$ 216,186
Available-for-sale securities	179,744	49,997
Working capital	496,394	193,751
Total assets	849,896	364,557
Convertible senior notes	281,761	281,126
Common stock and additional paid-in capital	1,752,992	1,174,989
Total stockholders' equity (deficit)	343,793	(3,634)

Other Data

(Unaudited, in thousands)

	Six Months Ended June 30,	
	2017	**2016**
Net cash used in operating activities	(149,541)	$ (151,670)
Share Based Compensation Expense	19,563	$ 20,542

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