Clovis Oncology Announces First Quarter 2017 Operating Results

May 3, 2017 4:06 PM ET

- *Strong Q1 launch quarter for Rubraca® (rucaparib) in U.S. with $7M reported in net sales*
- *Clovis notified that ARIEL3 target progression events achieved in mid-April*
- *Top-line ARIEL3 data anticipated by end of June*
- *Multiple clinical trials initiated in early 2017, including TRITON2 and TRITON3 in prostate cancer and Roche-sponsored rucaparib-atezolizumab combination study in gynecologic cancers*
- *Rucaparib E.U. Marketing Authorization Application under review; establishing E.U. organization to support potential Q1 2018 European launch*

BOULDER, Colo.--(BUSINESS WIRE)--May 3, 2017-- Clovis Oncology, Inc. (NASDAQ:CLVS) reported financial results for the quarter ended March 31, 2017, and provided an update on the Company's clinical development programs and regulatory outlook for the remainder of 2017.

"This is an exciting time at Clovis, with a robust U.S. launch of Rubraca underway, ARIEL3 topline results expected by the end of June, and our efforts underway to prepare for a potential E.U. launch early next year," said Patrick J. Mahaffy, President and CEO of Clovis Oncology. "In addition, we continue to expand our clinical development program for rucaparib in other indications where rucaparib may provide benefit to patients, either as monotherapy or in combination with other agents."

First Quarter 2017 Financial Results

For the first time, Clovis reported a full quarter of product revenue for Rubraca, following the approval and launch on December 19, 2016. Net product revenue for the first quarter was $7.0 million. The Company has seen strong uptake in the market with over 350 new patients starting therapy and over 300 unique healthcare providers prescribing during the quarter.

Clovis had $408.8 million in cash, cash equivalents and available-for-sale securities as of March 31, 2017. Cash used in operating activities was $80.4 million for the first quarter of 2017, compared with $83.7 million in first quarter of 2016. Clovis had approximately 44.8 million shares of common stock outstanding as of March 31, 2017. In January 2017, the Company raised net proceeds of $221.2 million through an offering of 5.75 million shares of common stock.

Clovis reported a net loss for the first quarter of 2017 of $58.5 million, or a net loss of $1.33 per share, compared with $83.4 million or a net loss of $2.17 per share for the first quarter of 2016. Net loss for the first quarter of 2017 included share-based compensation expense of $8.9 million, compared to $11.0 million in the first quarter of 2016.

Research and development expenses totaled $32.4 million for the first quarter of 2017, and $74.6 million for the comparable period 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 $29.2 million for the first quarter of 2017, compared to $9.8 million for the first quarter of 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.

Key Milestones and Objectives for Rucaparib

ARIEL3 Timing and Regulatory Updates

Upon notification from the Independent Data Monitoring Committee in mid-April that the target number of progression events in the mutant BRCA population has been achieved, Clovis has initiated final activities in preparation for database lock and release of top-line ARIEL3 results. Top-line results from ARIEL3 are now anticipated by the end of June. Results from the trial remain blinded until the database lock occurs.

Following announcement of top-line data, Clovis plans to provide a more comprehensive presentation of the ARIEL3 results in a scientific session at a medical meeting later this year. Pending positive data, the Company intends to submit a supplemental New Drug Application (sNDA) for a second line or later maintenance treatment indication, within approximately four months after the database lock.

The ARIEL3 pivotal study is a randomized, double-blind study comparing the effects of rucaparib against placebo to evaluate whether rucaparib given as a maintenance treatment to platinum-sensitive patients can extend the period of time for which the disease is controlled after a response to platinum-based chemotherapy. Patients who have high-grade serous ovarian cancer and have had at least two prior lines of platinum-based chemotherapies are randomized 2:1 to receive either rucaparib or placebo and the primary endpoint of the study is progression free survival, or PFS.

The primary efficacy analysis will evaluate, in a step-down manner, BRCA-mutant patients, all patients with a homologous recombination deficiency, or HRD, signature (including BRCA and non-BRCA), followed by all patients. In addition, a pre-specified subgroup analysis is planned to evaluate patients with low volume or no residual disease at baseline, to determine the impact of disease burden on PFS. Importantly, this analysis will also estimate the size of the population with tumor lesions greater than 2 centimeters still present after a partial response to second or later-line platinum therapy.

Pending positive results, the ARIEL3 trial is expected to serve as a confirmatory trial for Rubraca, which was approved under the FDA's accelerated approval program in December 2016; the approval was based on objective response rate and duration of response results from two multicenter, single-arm, open-label clinical trials, Study 10 and ARIEL2 Parts 1 and 2. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

The Company has an additional confirmatory study in the treatment setting, ARIEL4, which is open for enrollment. ARIEL4 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.

Clovis' Marketing Authorization Application (MAA) for rucaparib to the European Medicines Agency for the same 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, an approval would follow shortly thereafter.

New Collaborations

In February, Clovis entered into an agreement with Strata Oncology to accelerate patient identification and enrollment in the TRITON prostate cancer development program. The Strata trial is an observational study that provides no-cost tumor sequencing to patients at participating clinical sites, and under this agreement, match BRCA and ATM mutated advanced prostate cancer patients to Clovis' TRITON studies. Strata has agreed not to provide similar matching services on behalf of any other Strata collaborator for any other metastatic castrate-resistant prostate cancer (mCRPC) clinical trial with respect to patients having those same genetic mutations.

In late April, Clovis and Myriad Genetics, Inc. announced a companion diagnostic collaboration to support a post-marketing regulatory commitment related to Rubraca. Under the agreement, Myriad will submit a supplementary premarket approval (sPMA) application under its existing *PMA for BRACAnalysis CDx* to include Rubraca. The Myriad sPMA submission will fulfill a post-approval regulatory commitment by Clovis Oncology to the Food and Drug

Administration (FDA) for Rubraca, which was approved in December 2016, for women with advanced ovarian cancer who have been treated with two or more chemotherapies and whose tumors have a deleterious *BRCA* mutation as identified by an FDA-approved companion diagnostic test. The companion diagnostic test approved with Rubraca does not discriminate between germline and somatic mutations. Knowledge of germline status is important to provide patients appropriate counseling.

Recent Medical Meeting Presentations

In March, new data from the ARIEL2 study of rucaparib were presented at the 2017 Society of Gynecologic Oncology (SGO) Annual Meeting on Women's Cancer, including an integrated summary of data in patients from ARIEL2 parts 1 and 2 with a germline or somatic *BRCA1 or BRCA2* (*BRCA)* mutation, and separately, analyses of patient subsets from the ARIEL2 trial.

The integrated summary of data in patients from ARIEL2, the abstract for which was selected as the recipient of the 2017 SGO Presidential Award, analyzed objective response rate (ORR) and progression-free survival (PFS) in the 134 ovarian cancer patients with a germline or somatic *BRCA* mutation enrolled in ARIEL2, as well as the effect of platinum sensitivity status and prior lines of therapy on these endpoints. These data demonstrate that the objective response rate (ORR), disease control rate (DCR) and median progression-free survival (PFS) in patients with a *BRCA* mutation were greatest in platinum-sensitive patients, followed in descending order by those who were platinum-resistant, and those who were platinum-refractory.

This presentation also discussed the potential role of secondary somatic mutations restoring *BRCA* function as a mechanism of platinum resistance in patients with platinum-resistant or -refractory disease. Published data have shown that secondary mutations in *BRCA* are more frequently observed in platinum-resistant patients than platinum-sensitive patients. Data presented show that the presence of secondary somatic *BRCA* mutations may be a better predictor of rucaparib efficacy than prior responsiveness to platinum-based chemotherapy in patients with platinum-resistant or -refractory disease.

The second presentation at SGO discussed an analysis of *BRCA1* and *RAD51C* hypermethylation among archival and pretreatment biopsies from part 1 of the ARIEL2 study. The analysis demonstrated that, among ovarian cancer patients, methylation of *BRCA1* and *RAD51C* is associated with high loss of heterozygosity (LOH), consistent with the HRD phenotype. Further, methylation of *BRCA1* and *RAD51C* appear to confer sensitivity to rucaparib, as do mutations of *CDK12*. These data suggest that methylation is more reliably assessed in pretreatment than archival tumor samples. Furthermore, analysis of baseline samples from ARIEL2 suggests that routine sequencing of high-grade ovarian cancer tumor tissue biopsies would identify at least 10-15 percent of women with a somatic mutation and 20 percent of women with a germline mutation whose tumors might be sensitive to rucaparib.

In April, rucaparib preclinical data were presented at the American Association for Cancer Research (AACR) Annual Meeting 2017, providing greater insight into the mechanism of action and function of rucaparib in multiple disease and therapy settings, including prostate cancer and in combination with an anti-PDL1 in ovarian cancer.

The posters and presentations from SGO and AACR can be accessed at http://clovisoncology.com/pipeline/scientific-presentations/.

Rucaparib Clinical Development

In addition to ARIEL3 and ARIEL4 mentioned above, 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 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.
- 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 bevacizumab in combination as a first-line maintenance therapy for advanced ovarian cancer, which is expected to begin enrolling patients by year-end; and
- An additional 17 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 and urothelial cancers.

Conference Call Details

Clovis will hold a conference call to discuss first quarter 2017 results this afternoon, May 3, 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: **11635860**.

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. The MAA submission in Europe for an ovarian cancer treatment indication was submitted and accepted during the fourth quarter of 2016. Additionally, rucaparib is being developed as maintenance treatment for ovarian cancer in the ARIEL3 trial for patients with tumors with BRCA mutations and other DNA repair deficiencies beyond BRCA, as well as biomarker negative patients. Topline results from ARIEL3 are expected by late June, which, pending positive data, is expected to be followed by the submission of a sNDA for a second line or 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. Studies open for enrollment or under consideration include prostate, breast, pancreatic, gastroesophageal, bladder and lung cancers. 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
(in thousands, except per share amounts)

	Three Months Ended March 31,	
	2017	**2016**
Revenues:		
Product revenue, net	$ 7,045	$ -
Operating expenses:		
Cost of sales - product	1,163	-
Cost of sales - intangible asset amortization	372	-
Research and development	32,447	74,608
Selling, general and administrative	29,224	9,827
Change in fair value of contingent purchase consideration	-	516
Total expenses	63,206	84,951
Operating loss	(56,161)	(84,951)
Other income (expense):		
Interest expense	(2,581)	(2,104)
Foreign currency losses	(159)	(551)
Other income	354	25
Other income (expense), net	(2,386)	(2,630)

Loss before income taxes	(58,547)	(87,581)
Income tax benefit	83	4,181
Net loss	$ (58,464)	$ (83,400)
Basic and diluted net loss per common share	$ (1.33)	$ (2.17)
Basic and diluted weighted-average common shares outstanding	44,039	38,360

CONSOLIDATED BALANCE SHEET DATA
(in thousands)

	March 31, 2017	**December 31, 2016**
Cash and cash equivalents	$ 276,049	$ 216,186
Available-for-sale securities	132,778	49,997
Working capital	369,950	213,813
Total assets	536,614	364,557
Convertible senior notes	281,443	281,126
Common stock and additional paid-in capital	1,410,834	1,174,989
Total stockholders' equity (deficit)	174,209	(3,634)

Other Data
(in thousands)

	Three Months Ended March 31,	
	2017	**2016**
Net cash used in operating activities	(80,439)	$ (83,738)
Share Based Compensation Expense	8,947	$ 10,965

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Source: Clovis Oncology

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