NEWS RELEASE

# Clovis Oncology Announces First Quarter 2019 Operating Results

5/7/2019

- $33.1M in Rubraca ® (rucaparib) global sales for the first quarter of 2019
- Updated data on 52 patients with BRCA-mutant mCRPC provided to FDA; RECIST response rate highly consistent with that shown at ESMO 2018
- Targeting late 2019 for supplemental NDA filing for BRCA-mutant advanced prostate cancer; data update expected at Fall 2019 medical meeting
- Clovis-sponsored combination studies of lucitanib with rucaparib and Bristol-Myers Squibb's Opdivo expected to begin in mid-2019;
- Entered into non-dilutive clinical trial financing up to $175M to fund quarterly expenses related to the ATHENA clinical trial beginning Q2 2019
- Financing extends Clovis' projected cash runway into 2022
- $406.8M in cash, cash equivalents and available for sale securities at March 31, 2019

BOULDER, Colo.--(BUSINESS WIRE)-- **Clovis Oncology**, Inc. (NASDAQ:CLVS) reported financial results for the quarter ended March 31, 2019, and provided an update on the Company's **clinical development programs** and regulatory and commercial outlook for the rest of the year.

"We are pleased with our progress during the first quarter," said Patrick J. Mahaffy, President and CEO of Clovis Oncology. "With solid sales performance, an encouraging update of our TRITON prostate cancer data in support of our planned supplemental NDA in late 2019, the expected near-term initiation of two lucitanib combination studies and a successful financing that extends our projected cash runway into 2022, we are very enthusiastic about our progress toward our 2019 goals. In addition, I am pleased to announce that Dan Muehl, our Executive Vice President Finance, has been promoted to Chief Financial Officer. Dan has been with the Company for about four years and this is an extremely well-deserved promotion. "

## First Quarter 2019 Financial Results

Clovis reported product revenue for Rubraca of $33.1 million for the first quarter of 2019, which included U.S. product revenue of $31.9 million and ex-U.S. product revenue of $1.2 million, as compared to net product revenue for the quarter ended March 31, 2018 of $18.5 million. During the first quarter, the supply of free drug distributed to eligible patients through the Rubraca patient assistance program in the U.S. was approximately 21 percent of overall commercial supply compared to 22 percent in the first quarter of 2018. This represented $8.4 million in commercial value for the first quarter of 2019 compared to $5.1 million in the first quarter of 2018. Rubraca was initially approved in the ovarian cancer treatment setting in the U.S. in December 2016 and in the EU in May 2018. The Rubraca label was expanded to include the broader and earlier-line maintenance treatment indication in the U.S. in April 2018 and in the EU in January 2019.

Clovis had $406.8 million in cash, cash equivalents and available-for-sale securities as of March 31, 2019. Cash used in operating activities was $98.5 million for the first quarter of 2019, compared with $100.6 million for the first quarter of 2018. This includes product supply costs of $27.5 million in the first quarter of 2019, compared to $31.5 million for the comparable period in 2018. Cash used also includes a $15 million milestone payment in the first quarter of 2019 related to the EU maintenance indication approval. There were no such milestone payments in the first quarter of 2018. Clovis had approximately 53.0 million shares of common stock outstanding as of March 31, 2019.

Clovis reported a net loss for the first quarter of 2019 of $86.4 million, or ($1.63) per share, compared to the net loss for the first quarter of 2018 which was $77.7 million, or ($1.54) per share. Net loss for the first quarter of 2019 included share-based compensation expense of $13.6 million, compared to $11.9 million for the first quarter of 2018.

Research and development expenses totaled $62.0 million for the first quarter of 2019, compared to $43.5 million for the first quarter of 2018. The increase year over year is primarily due to higher research and development costs for rucaparib clinical trials, including increased enrollment in ongoing ovarian and prostate studies, increased costs related to initiating new ovarian and bladder studies during 2018, as well as additional headcount to support these increased rucaparib clinical trial activities.

Selling, general and administrative expenses totaled $47.8 million for the first quarter of 2019, compared to $39.3 million for the comparable period in 2018. The increase year over year is primarily due to higher selling, general and administrative expenses related to the commercialization of Rubraca in the U.S. and the EU, including facility expenses and personnel expenses associated with expanding the EU infrastructure.

Clovis recently entered into an agreement for up to $175 million in non-dilutive clinical trial financing with certain affiliates of TPG Sixth Street Partners to reimburse Clovis' costs and expenses related to the ATHENA clinical trial. ATHENA is Clovis Oncology's largest clinical trial, with a planned target enrollment of 1,000 patients across more than 270 sites in at least 25 countries. For further details, please see the Clovis news release and report on Form 8-K, dated May 2, 2019 available on the Company's website.

## Key Milestones and Objectives for Rubraca

### Recurrent Ovarian Cancer Maintenance Treatment Indication Approved in the EU and Launched in Germany and UK

In January 2019, the European Commission (EC) approved the use of Rubraca for its second indication, as monotherapy for the maintenance treatment of adults with platinum-sensitive relapsed high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to platinum-based chemotherapy. With this approval, Rubraca's indication is expanded beyond its initial marketing authorization in the EU granted in May 2018, and in this indication Rubraca is available to eligible patients regardless of their BRCA mutation status. Rubraca is the first PARP inhibitor licensed for an ovarian cancer treatment indication in Europe and is the first to be available for both treatment and maintenance treatment among eligible patients with ovarian cancer. Clovis launched Rubraca in Germany and in the private pay market in the UK in March and anticipates launching in other EU countries later in 2019 and 2020.

### Regulatory Path for Supplemental NDA in BRCA-mutant Advanced Prostate Cancer

Initial data from the Company's ongoing TRITON studies of Rubraca in advanced prostate cancer were presented at the ESMO 2018 Congress (European Society for Medical Oncology) in October 2018. The initial TRITON2 data showed a 44 percent confirmed objective response rate (ORR) by investigator assessment in 25 RECIST1/PCWG3** response-evaluable patients with a BRCA1/2 alteration, and results by independent assessment were consistent. The median duration of response in these patients had not yet been reached. In addition, a 51 percent confirmed prostate specific antigen (PSA) response rate was observed in 45 PSA response-evaluable patients with a BRCA1/2 alteration. Preliminary safety data for Rubraca in men with mCRPC were consistent with those observed in patients with ovarian cancer and other solid tumors.

The TRITON2 results were the basis for Breakthrough Therapy designation for Rubraca as a monotherapy treatment of adult patients with BRCA1/2 mutant mCRPC who have received at least one prior androgen receptor (AR)-directed therapy and taxane-based chemotherapy, which was granted on October 1, 2018 by the U.S. Food and Drug Administration (FDA). Both studies in the TRITON program, TRITON2 and TRITON3, continue to enroll patients.

As a result of Rubraca's breakthrough therapy status, Clovis agreed to provide regular updates to FDA on the Company's advanced prostate cancer development program on a regular basis. At the end of April 2019, Clovis provided an update to FDA on 52 patients with BRCA-mutant mCRPC that showed a RECIST response rate and PSA response highly consistent with the data presented at ESMO 2018. Clovis expects to discuss this update with FDA in the next several weeks. Clovis intends to file the planned supplemental NDA by the end of 2019.

## Rubraca Clinical Development

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

- ARIEL4, a confirmatory study in the ovarian cancer treatment setting, is a Phase 3 multicenter, randomized study of Rubraca versus chemotherapy in relapsed ovarian cancer patients with BRCA mutations who have failed two prior lines of therapy. This study is currently enrolling patients.
- ATHENA is a Phase 3 study in advanced ovarian cancer in the first-line maintenance treatment setting evaluating Rubraca plus Opdivo® (PD-1 inhibitor), Rubraca, 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 currently enrolling patients.
- TRITON3 is a Phase 3 comparative study in mCRPC enrolling BRCA-mutant and ATM-mutant (both inclusive of germline and somatic) patients who have progressed on androgen-receptor (AR)-targeted therapy and who have not yet received chemotherapy in the castration-resistant setting. TRITON3 compares Rubraca to physician's choice of AR-targeted therapy or chemotherapy in these patients. This study is currently enrolling patients.
- TRITON2 is a Phase 2 single-arm study in mCRPC in patients with BRCA mutations (inclusive of germline and somatic), which is also enrolling patients with deleterious mutations of other homologous recombination (HR) repair genes. All patients will have progressed after receiving one line of taxane-based chemotherapy and one or two lines of AR-targeted therapy. This study is currently enrolling patients. Updated data from the ongoing TRITON2 study are anticipated at a Fall 2019 medical meeting.
- RUCA-J study is a Phase 1 study which has identified the 600mg BID dose of rucaparib as the recommended dose in Japanese patients; this will enable development of a bridging strategy and potential inclusion of Japanese sites in planned or ongoing global studies. This study is currently enrolling patients.
- ARIES is a Phase 2, open-label, multi-cohort study evaluating the combination of Rubraca and Opdivo in patients with relapsed ovarian cancer. This study is expected to begin enrolling patients in the first half of

2019.

- SEASTAR is a Phase 1b/2 study comprised of multiple single-arm rucaparib combination studies, which currently includes the following planned combinations:
    - Rubraca and lucitanib, Clovis' investigational inhibitor of multiple tyrosine kinases including VEGFR, for the treatment of ovarian cancer, expected to begin in mid-2019;
    - Rubraca and sacituzumab govitecan, an antibody drug conjugate, for the treatment of advanced metastatic triple-negative breast cancer, relapsed platinum-resistant ovarian cancer and potentially advanced metastatic urothelial cancers, is expected to begin enrolling patients in 2019;
- And a planned Phase 2 pan-tumor study in patients with multiple tumor types with a mutation in certain genes likely to confer sensitivity to Rubraca, which is expected to begin by year-end 2019.

Also, a Phase 2 combination study of Opdivo with Rubraca for the treatment of mCRPC is underway. This study, sponsored by Bristol-Myers Squibb, is being conducted as an arm in the CHECKMATE 9KD prostate cancer study, and is currently enrolling patients. Exploratory studies in other tumor types are also underway, as well as active discussions with Bristol-Myers Squibb regarding additional potential combination studies.

## Lucitanib Clinical Development

Lucitanib is an investigational, oral, potent inhibitor of the tyrosine kinase activity of vascular endothelial growth factor receptors 1 through 3 (VEGFR1-3), platelet-derived growth factor receptors alpha and beta (PDGFRα/β) and fibroblast growth factor receptors 1 through 3 (FGFR1-3), which was previously evaluated in breast and lung cancers in partnership with Servier. Clovis has global rights (excluding China) for lucitanib.

Recent data for a drug that inhibits these same three pathways - when combined with a PD-1 inhibitor - are extremely encouraging and represent a scientific rationale for the development of lucitanib in combination with a PD-1 inhibitor, and a Clovis-sponsored study of lucitanib in combination with Opdivo is planned in gynecologic and other tumor types. Clovis also intends to initiate a study of lucitanib in combination with rucaparib in ovarian cancer as an arm of the SEASTAR study mentioned above, based on encouraging data of VEGF and PARP inhibitors in combination. Each of these Phase 1b/2 studies is expected to initiate in mid-2019.

During the second quarter, Clovis and Alkermes initiated a preclinical research collaboration to evaluate ALKS 4230, Alkermes' investigational engineered interleukin-2 (IL-2) variant immunotherapy, in combinations with rucaparib and lucitanib.

## Conference Call Details

Clovis will hold a conference call to discuss First Quarter 2019 results this morning, May 7, 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 877.698.7048, International participants 647.689.5448, conference ID: 8567356.

## About Rubraca (rucaparib)

Rubraca 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, and lung cancers. Clovis holds worldwide rights for Rubraca.

In the United States, Rubraca 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. Rubraca 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 Rubraca.

In the EU, Rubraca is approved for the maintenance treatment of adults with platinum-sensitive relapsed high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to platinum-based chemotherapy. This expands rucaparib's indication beyond its initial marketing authorization in the EU granted in May 2018 and with this label expansion, rucaparib is now available to patients regardless of their BRCA mutation status. Rubraca is also approved in the EU for the 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.

Rubraca is an unlicensed medical product outside of the U.S. and the 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, for those indications that require them, 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, with additional office locations in the U.S. and Europe. Please visit **www.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. Examples of forward-looking statements contained in this press release include, among others, statements regarding our plans for commercial launch in additional countries, expectations for submission of regulatory filings, our plans to present final or interim data on ongoing clinical trials, our plans to submit additional data to, or meet with, the FDA with respect to the status of or plans for ongoing or planned trials, the timing and pace of commencement of and enrollment in our clinical trials and the cost of certain trials, including those being considered, planned or conducted in collaboration with partners, our plans for commencement of additional planned trials, the potential results of such clinical trials, changes in drug supply timing and costs and other expenses and statements regarding our expectations of the supply of free drug distributed to eligible patients and our expectations regarding the total amount of funding that may be available to us under the agreement with TPG Sixth Street Partners. 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 and therapeutic approaches, the performance of our third-party manufacturers, our clinical development programs for our drug candidates and those of our partners, whether future study results will be consistent with study findings to date and whether future study results will support continued development or regulatory approval, the corresponding development pathways of our companion diagnostics, the timing of availability of data from our clinical trials and the results, the initiation, enrollment, timing and results of our planned clinical trials, the risk that final results of ongoing trials may differ from initial or interim results as a result of factors such as final results from a larger patient population may be different from initial or interim results from a smaller patient population, actions by the FDA, the EMA or other regulatory authorities regarding data required to support drug applications and whether to accept or approve drug applications that may be filed, as well as their decisions regarding drug labeling, reimbursement and pricing, and other matters that could affect the development, 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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1 Response Evaluation Criteria in Solid Tumors (RECIST) is a standardized methodology for determining therapeutic response to anticancer therapy using changes in lesion appearance on imaging studies.

** Prostate Cancer Working Group (PCWG3) is an international expert committee of prostate cancer clinical investigators who have recommended modifications to RECIST for use in the conduct of trials in metastatic castration-resistant prostate cancer (mCRPC) which were adopted in the

TRITON2 protocol.

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

| | Three Months Ended March 31, | |
|---|---|---|
| | 2019 | 2018 |
| Revenues: | | |
| Product revenue | $ 33,118 | $ 18,523 |
| Operating expenses: | | |
| Cost of sales - product | 7,405 | 4,006 |
| Cost of sales - intangible asset amortization | 1,120 | 372 |
| Research and development | 62,031 | 43,543 |
| Selling, general and administrative | 47,761 | 39,274 |
| Total expenses | 118,317 | 87,195 |
| Operating loss | (85,199) | (68,672) |
| Other income (expense): | | |
| Interest expense | (3,590) | (2,635) |
| Foreign currency loss | (192) | (81) |
| Legal settlement loss | - | (7,975) |
| Other income | 2,400 | 1,409 |
| Other income (expense), net | (1,382) | (9,282) |
| Loss before income taxes | (86,581) | (77,954) |
| Income tax benefit | 160 | 260 |
| Net loss | $ (86,421) | $ (77,694) |
| Basic and diluted net loss per common share | $ (1.63) | $ (1.54) |
| Basic and diluted weighted-average common shares outstanding | 52,891 | 50,602 |

RECONCILIATION OF GAAP TO NON-GAAP
NET LOSS AND NET LOSS PER SHARE
(Unaudited, in thousands, except per share amounts)

| | Three Months Ended March 31, | |
|---|---|---|
| | 2019 | 2018 |
| GAAP net loss | $ (86,421) | $ (77,694) |
| Adjustments: | | |
| Legal settlement loss (1) | - | 7,975 |
| Non-GAAP net loss | $ (86,421) | $ (69,719) |
| GAAP net loss per common share | $ (1.63) | $ (1.54) |
| Non-GAAP net loss per common share | $ (1.63) | $ (1.38) |

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 March 31, 2018, the Company recorded a one-time charge of $8.0 million related to an agreement to resolve a potential litigation claim against us and certain of our officers.

CONSOLIDATED BALANCE SHEET DATA
(Unaudited, in thousands)

| | March 31, 2019 | December 31, 2018 |
|---|---|---|
| Cash and cash equivalents | $ 123,308 | $ 221,876 |
| Available-for-sale securities | 283,474 | 298,270 |
| Working capital | 360,655 | 446,550 |
| Total assets | 784,617 | 863,560 |
| Convertible senior notes | 576,003 | 575,470 |
| Common stock and additional paid-in capital | 2,048,928 | 2,034,195 |
| Total stockholders' equity | 74,851 | 146,469 |

Other Data
(Unaudited, in thousands)

| | Three Months Ended March 31, | |
|---|---|---|
| | 2019 | 2018 |
| Net cash used in operating activities | (98,451) | (100,635) |
| Share Based Compensation Expense | 13,640 | 11,913 |

Other Information
($ in millions)

| | |
|---|---|
| Share-based compensation Q1 2019 | 13.6 |
| Share-based compensation Q1 2018 | 11.9 |
| Net cash used in operating activities Q1 2019 | (98.5) |
| Net cash used in operating activities Q1 2018 | (100.6) |

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