NEWS RELEASE

Clovis Oncology Announces Second Quarter 2019 Operating Results

8/1/2019

- $33.0M in Rubraca® (rucaparib) net product revenue for Q2 2019 compared to $23.8M for Q2 2018
- U.S. sales increased 3% sequentially in Q2 2019 over Q1 2019
- Global net product revenue guidance of $137 million to $147 million provided for the full year 2019
- Updated data from TRITON2 study of patients with BRCA-mutant mCRPC to be provided to FDA later this month; RECIST and PSA response rates consistent with those shown at ESMO 2018
- TRITON2 data to be presented at ESMO 2019 in poster discussion session in late September
- Supplemental NDA for Rubraca in BRCA-mutant advanced prostate cancer on track for Q4 2019
- Phase 1b/2 combination study of lucitanib with Rubraca now enrolling; dose-finding cohort underway, expansion cohort to focus on advanced ovarian cancer
- Phase 1b/2 combination study of lucitanib and Bristol Myers-Squibb's Opdivo now enrolling; dose-finding cohort to be followed by expansion cohorts in advanced gynecologic cancers and other solid tumors
- New BMS-sponsored Phase 2 combination study of Opdivo and Yervoy with Rubraca for the treatment of advanced gastric cancer planned to initiate in Q4 2019
- Cash burn to significantly reduce in 2H 2019 and 2020 based on lower milestone and product supply costs and anticipated revenue growth; further supported by ATHENA clinical trial financing

BOULDER, Colo.--(BUSINESS WIRE)-- **Clovis Oncology**, Inc. (NASDAQ:CLVS) reported financial results for the quarter ended June 30, 2019, and provided an update on Clovis' **clinical development programs** and regulatory and commercial outlook for the second half of 2019.

"We continue to make progress in the second-line ovarian cancer maintenance indication in the U.S., and we look forward to the potential prostate indication in the U.S. and launches in additional EU countries to support top-line growth in 2020," said Patrick J. Mahaffy, CEO and President of Clovis Oncology. "In addition, we are extremely pleased to have begun our combination studies of lucitanib plus Rubraca and lucitanib plus Opdivo, and we look forward to sharing initial data from these studies at medical meetings next year. We believe these combinations

have significant potential and in almost every case, will study unselected or all-comer populations."

Second Quarter 2019 Financial Results

Clovis reported net product revenue for Rubraca of $33.0 million for Q2 2019, which included U.S. net product revenue of $32.7 million and ex-U.S. net product revenue of $0.3 million, compared to net product revenue for Q2 2018 of $23.8 million. U.S. net product revenue increased three percent sequentially from Q1 2019 to Q2 2019. Ex-US net product revenues were lower sequentially in Q2 2019 than Q1 2019, as initial launch stocking shipments were made in March and reported in Q1 product revenue. Clovis expects ex-U.S. net product revenues to increase in Q3 compared to Q2 2019.

Clovis expects global net product revenue to be in the range of $137 million to $147 million for the full year.

The supply of free drug distributed to eligible patients through the Rubraca patient assistance program for Q2 2019 was marginally higher at approximately 22 percent of the overall commercial supply, compared to 21 percent in Q1 2019 and lower than the 25 percent reported in Q2 2018. This represented $9.3 million in commercial value for Q2 2019 compared to $8.4 million in Q1 2019 and $7.9 million in Q2 2018.

Net product revenue for the first half of 2019 was $66.1 million, as compared to net product revenue of $42.3 million for the first half of 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. For the first half of 2019, the supply of free drug distributed to eligible patients was an additional approximately 21 percent of the overall commercial supply compared to 24 percent in the first half of 2018. This represented $17.7 million in commercial value for the first half of 2019 compared to $13.4 million in the first half of 2018.

Clovis had $315.9 million in cash, cash equivalents and available-for-sale securities as of June 30, 2019. Cash used in operating activities was $98.9 million for Q2 2019 and $197.4 million for the first half of 2019, compared with $110.2 million for Q2 2018 and $210.8 million for the first half of 2018. For the first half of 2019, total cash used included product supply costs of $42.5 million and a $15.75 million milestone payment to Pfizer related to the second European product approval in Q1 2019. For the first half of 2018, total cash used included product supply costs of $76.1 million and milestone payments to Pfizer of $58.0 million in Q2 2018 related to U.S. product approvals in December 2016 and April 2018 and European product approval in May 2018.

The amount spent on product supply costs and milestone payments is expected to decrease substantially in the second half of 2019 and in 2020. These reduced costs, combined with anticipated net product revenue growth in the global ovarian indications and the potential U.S. prostate indication in 2020, will significantly reduce our cash burn in the second half of 2019 and 2020. This will be additionally supported by the quarterly cash payments provided by the ATHENA clinical trial financing.

Clovis reported a net loss for Q2 2019 of $120.4 million, or ($2.27) per share, and $206.9 million, or a net loss of ($3.91) per share for the first half of 2019. Net loss for Q2 2018 was $101.2 million, or ($1.94) per share, and $178.9 million, or a net loss of ($3.48) per share, for the first half of 2018. Net loss for Q2 and first half of 2019 included share-based compensation expense of $14.1 million and $27.8 million, compared to $14.9 million and $26.8 million for the comparable periods of 2018.

Research and development expenses totaled $70.7 million for Q2 2019 and $132.8 million for the first half of 2019, compared to $52.7 million and $96.3 million for the comparable periods in 2018. The increase is primarily due to higher research and development costs for rucaparib clinical trials. Clovis expects research and development costs to be higher for the full year 2019 compared to 2018. Thereafter, we expect research and development costs to

flatten, and then trend lower in the following years, as the largest of the Clovis' sponsored clinical trials near completion.

Selling, general and administrative expenses totaled $48.0 million for Q2 2019 and $95.8 million for the first half of 2019, compared to $44.9 million and $84.1 million for the comparable periods 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 EU. Clovis also expects selling, general and administrative costs to be higher for the full year 2019 compared to 2018, however, these costs will continue to increase modestly as Clovis prepares for anticipated product launches in a greater number of countries outside of the U.S. and launch activities for the anticipated prostate indication approval in 2020.

In May 2019, Clovis entered into an agreement for up to $175.0 million in non-dilutive clinical trial financing with certain affiliates of TPG Sixth Street Partners to reimburse Clovis' quarterly costs and expenses related to the ATHENA clinical trial. ATHENA is Clovis' largest clinical trial, with a planned target enrollment of 1,000 patients across more than 270 sites in at least 25 countries. Clovis plans to borrow amounts required to reimburse actual costs and expenses incurred during each quarter, beginning in Q2 2019, and repayment is anticipated to begin in 2022, the approximate anticipated timing of a potential Rubraca first-line maintenance approval in advanced ovarian cancer. The financing is secured by Rubraca assets, and Clovis maintains worldwide rights to Rubraca.

Rubraca in BRCA-mutant Advanced Prostate Cancer

Initial data from Clovis' ongoing TRITON studies of Rubraca in metastatic castrate-resistant prostate cancer (mCRPC) 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 mutationand 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 mutation. 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 updates to FDA on Clovis' advanced prostate cancer development program on a regular basis. Later this month, Clovis intends to provide an update to FDA on the TRITON2 data for patients with BRCA-mutant mCRPC. These data will show RECIST and PSA response rates consistent with the data presented at ESMO 2018. Clovis will present the TRITON2 data in a poster discussion session at the European Society for Medical Oncology (ESMO) Annual Meeting in Barcelona in late September. Clovis intends to file the planned supplemental New Drug Application (sNDA) during the fourth quarter 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 mCRPCenrolling 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.
- 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 currently enrolling patients.
- 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, is currently enrolling patients with locally advanced or metastatic solid tumors into the Phase 1b portion;
    - Rubraca and sacituzumab govitecan, an antibody drug conjugate, for the treatment of advanced metastatic triple-negative breast cancer, relapsed platinum-resistant ovarian cancer and advanced metastatic urothelial cancers, is expected to begin enrolling patients by year-end;
- And a planned Phase 2 pan-tumor study in patients with solid tumors associated with deleterious mutations in homologous recombination repair genes, 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. In addition, a new Phase 2 combination study of Opdivo and Yervoy with Rubraca for the treatment of advanced gastric cancer is planned to initiate in Q4 2019 and will be sponsored by Bristol-Myers Squibb.

Exploratory studies in other solid tumors 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). 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 underway in advanced gynecologic cancers and other solid tumors. Based on encouraging data of VEGF and PARP inhibitors in combination, a study of lucitanib in combination with rucaparib in advanced ovarian cancer is also underway as an arm of the SEASTAR study. Each of these Phase 1b/2 studies is currently enrolling patients.

As previously announced, Clovis and Alkermes have 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 Q2 2019 results this morning, August 1, at 8:30am ET. The conference call will be simultaneously webcast on the Clovis Oncology web site **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: 5192422.

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 Lucitanib

Lucitanib is an 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 (PDFGRα/β) and fibroblast growth factor receptors 1 through 3 (FGFR1-3). Emerging clinical data support the combination of angiogenesis inhibitors and immunotherapy to increase effectiveness in multiple cancer indications. Angiogenic factors, such as vascular endothelial growth factor (VEGF), are frequently up-regulated in tumors and create an immunosuppressive tumor microenvironment. Use of antiangiogenic drugs reverses this immunosuppression and can augment response to immunotherapy.

Lucitanib is an unlicensed medical product.

About Clovis Oncology

Clovis Oncology, Inc. is a biopharmaceutical second 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 future financial and operating performance, business plans or prospects, including expectations concerning continued revenue growth from sales of Rubraca, our share in the field of treatment and maintenance treatment of advanced ovarian cancer, our expenses and future cash position, 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 funding that may be available to us, and the timing of repayment, 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, changes in gross-to-net or free drug provided through our patient assistance program, the availability of reimbursement and insurance coverage, the performance of our third-party manufacturers, whether our clinical development programs for our drug candidates and those of our partners can be completed on time or at all, 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, their interpretations of our data and agreement with our regulatory approval strategies or components of our filings, including our clinical trial designs, conduct and methodologies, as well as their decisions regarding drug labeling, reimbursement and pricing, and other matters that could affect the development, approval, 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.

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 June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Revenues:				
Product revenue, net	$ 32,978	$ 23,757	$ 66,096	$ 42,279
Operating expenses:				
Cost of sales - product	6,445	4,490	13,851	8,495
Cost of sales - intangible asset amortization	1,217	709	2,337	1,080
Research and development	70,746	52,707	132,777	96,250
Selling, general and administrative	48,029	44,864	95,791	84,138
Total expenses	126,437	102,770	244,756	189,963
Operating loss	(93,459)	(79,013)	(178,660)	(147,684)
Other income (expense):				
Interest expense	(3,817)	(3,581)	(7,407)	(6,216)
Foreign currency loss	(226)	(104)	(419)	(185)
Legal settlement loss	(25,000)	(20,000)	(25,000)	(27,975)
Other income	1,899	1,475	4,300	2,883
Other income (expense), net	(27,144)	(22,210)	(28,526)	(31,493)
Loss before income taxes	(120,603)	(101,223)	(207,186)	(179,177)
Income tax benefit	176	33	336	292
Net loss	$ (120,427)	$ (101,190)	$ (206,850)	$ (178,885)
Basic and diluted net loss per common share	$ (2.27)	$ (1.94)	$ (3.91)	$ (3.48)
Basic and diluted weighted-average common shares outstanding	53,028	52,223	52,960	51,425

CONSOLIDATED BALANCE SHEET DATA
(Unaudited, in thousands)

	June 30, 2019	December 31, 2018
Cash and cash equivalents	$ 108,607	$ 221,876
Available-for-sale securities	207,306	298,270
Working capital	272,646	446,550
Total assets	685,975	863,560
Convertible senior notes	576,763	575,470
Common stock and additional paid-in capital	2,064,446	2,034,195
Total stockholders' equity (deficit)	(29,982)	146,469

Other Data
(Unaudited, in thousands)

	Six Months Ended June 30,	
	2019	2018
Net cash used in operating activities	(197,408)	(210,844)
Share Based Compensation Expense	27,769	26,768

Other Information
($ in millions)

Share-based compensation Q1 2019	13.7
Share-based compensation Q2 2019	14.1
Share-based compensation Q2 YTD 2019	27.8
Share-based compensation Q1 2018	11.9
Share-based compensation Q2 2018	14.9
Share-based compensation Q2 YTD 2018	26.8
Net cash used in operating activities Q1 2019	(98.5)
Net cash used in operating activities Q2 2019	(98.9)
Net cash used in operating activities Q2 YTD 2019	(197.4)
Net cash used in operating activities Q1 2018	(100.6)
Net cash used in operating activities Q2 2018	(110.2)
Net cash used in operating activities Q2 YTD 2018	(210.8)

View source version on **businesswire.com**: **https://www.businesswire.com/news/home/20190801005249/en/**

Breanna Burkart

303.625.5023

bburkart@clovisoncology.com

Anna Sussman

303.625.5022

asussman@clovisoncology.com

Source: Clovis Oncology, Inc.