



NEWS RELEASE

Clovis Oncology Announces Third Quarter 2019 Operating Results

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- \$37.6M in Rubraca® (rucaparib) net product revenue for Q3 2019, up 65% year over year
- Net product revenue increased 14% sequentially in Q3 2019 compared to Q2 2019, including sequential U.S. sales increase of 12%
- Increased FY2019 global net product revenue guidance to \$141M-\$147M
- Q3 2019 operating cash burn reduced from Q2 2019 by 42%; net cash burn reduced to \$45M
- \$354.1M in cash, cash equivalents and available for sale securities at September 30, 2019; anticipated cash runway into 2H 2021
- Supplemental NDA for Rubraca in patients with BRCA1/2-mutant advanced prostate cancer to be filed before year-end
- Lucitanib combination studies enrolling; initial data anticipated at medical meetings beginning mid-2020
- Acquired rights to FAP-2286, radiopharmaceutical targeting FAP; Clovis currently planning to file IND in 2H 2020

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

"We are extremely pleased with our progress made on all fronts during the third quarter. We reported encouraging quarter-over-quarter revenue growth in the U.S. and in October launched in England with reimbursement now provided via the Cancer Drugs Fund," said Patrick J. Mahaffy, CEO and President of Clovis Oncology. "The TRITON2 prostate data presented at ESMO were very encouraging, and we remain on track to file the supplemental New Drug Application for patients with a BRCA1/2 mutation in advanced prostate cancer before year-end. We are pleased that the lucitanib combination studies are now enrolling patients, in particular the combination with nivolumab. And finally, we look forward to providing updates for FAP-2286, our recently-licensed FAP-targeted radiopharmaceutical compound, as we move this preclinical candidate forward."

Third Quarter 2019 Financial Results

Clovis reported net product revenue for Rubraca of \$37.6 million for Q3 2019, which included U.S. net product revenue of \$36.5 million and ex-U.S. net product revenue of \$1.1 million, compared to net product revenue for Q3 2018 of \$22.8 million. Total revenue increased 14 percent sequentially from Q2 2019 to Q3 2019, including a 12 percent increase in U.S. revenues.

Clovis now expects global net product revenue to be in the range of \$141 million to \$147 million for the full year 2019.

The supply of free drug distributed to eligible patients through the Rubraca patient assistance program for Q3 2019 was lower at 20 percent of the overall commercial supply, compared to 22 percent in Q2 2019 and 30 percent reported in Q3 2018. This represented \$9.0 million in commercial value for Q3 2019 compared to \$9.6 million in Q3 2018.

Net product revenue for the first nine months of 2019 was \$103.7 million, as compared to net product revenue of \$65.0 million for the first nine months of 2018. For the nine-month period ended September 30, 2019 the supply of free drug distributed to eligible patients was an additional approximately 21 percent of the overall commercial supply compared to 26 percent in the first nine months of 2018. This represented \$26.7 million in commercial value for the nine months ended September 30, 2019, compared to \$23.0 million in the comparable period in 2018.

Clovis had \$354.1 million in cash, cash equivalents and available-for-sale securities as of September 30, 2019. In August 2019, Clovis completed a private placement sale of \$263.0 million aggregate principal amount of 4.50 percent convertible senior notes due 2024. The net proceeds from the offering were \$255.0 million, after deducting underwriting discounts and commissions, and offering expenses. A portion of the proceeds, totaling \$171.8 million, were used to repurchase \$190.3 million of par value of convertible senior notes due 2021, with the remainder of \$83.2 million to be used for general corporate purposes. As of September 30, 2019, the Company also had up to \$154 million remaining to draw under the TPG ATHENA clinical trial financing agreement to fund the expenses of the ATHENA trial through Q3 2022.

Based on the Company's anticipated revenues, spending, available financing sources and existing cash, cash equivalents and available-for-sale securities, the Company believes it has sufficient cash, cash equivalents and available-for-sale securities to fund its operating plan into the second half of 2021. This does not include any cash repayment that may be required to pay off (unless refinanced earlier) the remaining \$97 million principal amount of convertible notes at their maturity due September 2021.

Cash used in operating activities was \$57.0 million for Q3 2019 and \$253.5 million for the first nine months of 2019,

compared with \$72.5 million for Q3 2018 and \$283.3 million for the comparable period in 2018. Cash used in operations decreased year over year for Q3 2019 and the first nine months of 2019 and dropped 42 percent sequentially from \$98.0 million in Q2 2019 to \$57.0 million in Q3 2019. The TPG ATHENA financing provided \$12.2 million in cash in Q3 2019, resulting in a net cash reduction in Q3 2019 of \$44.8 million. For the first nine months of 2019, total cash used included product supply costs of \$42.5 million and a \$15.75 million milestone payment to Pfizer and for the comparable period in 2018, total cash used included product supply costs of \$76.1 million and milestone payments to Pfizer of \$58.0 million.

Clovis reported a net loss for Q3 2019 of \$94.1 million, or (\$1.72) per share, and \$300.9 million, or a net loss of (\$5.62) per share for the first nine months of 2019. Net loss for Q3 2018 was \$89.9 million, or (\$1.71) per share, and \$268.8 million, or a net loss of (\$5.18) per share, for the comparable period in 2018. Net loss for Q3 and the first nine months of 2019 included share-based compensation expense of \$14.0 million and \$41.7 million, compared to \$10.9 million and \$37.7 million for the comparable periods of 2018.

Research and development expenses totaled \$77.9 million for Q3 2019 and \$210.7 million for the first nine months of 2019, compared to \$63.9 million and \$160.1 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 trend lower for the full year starting in 2020 and in the following years, compared to 2019, as the largest of the Clovis-sponsored clinical trials near completion and as the Company reduces spending related to clinical programs and other activities.

Selling, general and administrative expenses totaled \$41.8 million for Q3 2019 and \$137.6 million for the first nine months of 2019, compared to \$42.5 million and \$126.6 million for the comparable periods in 2018. Selling, general and administrative expenses decreased year over year for Q3 2019 and also sequentially by 13 percent, from \$48.0 million in Q2 2019 to \$41.8 million in Q3 2019 based on cost reduction efforts by the Company.

Rubraca in BRCA1/2-mutant Advanced Prostate Cancer

Updated data from Clovis' ongoing TRITON2 study of Rubraca in metastatic castrate-resistant prostate cancer (mCRPC) were presented at the ESMO 2019 Congress (European Society for Medical Oncology) in September 2019. The data showed a 43.9 percent confirmed objective response rate (ORR) by investigator assessment in 57 RECIST1/PCWG32 response-evaluable patients with a BRCA1/2 mutation. When assessed by independent radiological review, which is the primary endpoint of the trial, the response rate was consistent (40.4 percent). In addition, a 52.0 percent confirmed prostate-specific antigen (PSA) response rate was observed in 98 response-evaluable patients with a BRCA1/2 mutation. Confirmed radiographic responses were durable, with 60 percent lasting 24 weeks or longer (15/25). The safety data for Rubraca in men with mCRPC were consistent with prior

reports from TRITON2 and for patients with ovarian cancer and other solid tumors.

The TRITON2 data presented at ESMO 2019 will be included in the filing of Clovis Oncology's planned supplemental NDA (sNDA) to the Food and Drug Administration (FDA) for Rubraca in BRCA1/2-mutant advanced prostate cancer, although the sNDA data set will also include additional patients, and additional data maturity on the patients reported at ESMO 2019. Clovis intends to file the planned sNDA for Rubraca in patients with BRCA1/2-mutant advanced prostate cancer 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 whose tumors have progressed on 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 whose tumors 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 received one previous line of taxane-based chemotherapy and one or two lines of AR-targeted therapy. 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 enrolling patients with solid tumors into the Phase 1b portion;
- 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 or early 2020.

Also, two additional Phase 2 combination studies sponsored by Bristol-Myers Squibb are underway or expected to initiate in the near-term:

- The combination of Opdivo with Rubraca for the treatment of mCRPC is being conducted as an arm in the CHECKMATE 9KD prostate cancer study, and is currently enrolling patients;
- The combination study of Opdivo and Yervoy with Rubraca for the treatment of advanced gastric cancer is being conducted as an arm of the FRACTION advanced gastric cancer study and is planned to initiate in early 2020.

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 (PDGFR α / 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, and initial data are anticipated at medical meetings beginning in mid-2020.

In addition, a Phase 1/2 combination study sponsored by Bristol-Myers Squibb will evaluate multiple combinations with Opdivo, including an arm in combination with lucitanib, in patients with stage IV non-small cell lung cancer that has spread or reoccurred after failure of chemotherapy and immunotherapy. This study is expected to start by the end of the year.

Newly-Licensed Peptide-Targeted Radionuclide Therapy Program, including FAP-2286

In September 2019, Clovis and 3B Pharmaceuticals GmbH (3BP) entered into a global licensing and collaboration

agreement with an initial focus on developing FAP-2286, a peptide-targeted radionuclide therapy (PTRT) and imaging agent targeting fibroblast activation protein alpha (FAP). FAP is highly expressed in many epithelial cancers, including more than 90 percent of breast, lung, colorectal and pancreatic carcinomas. Clovis will conduct global clinical trials and has obtained U.S. and global rights, excluding Europe (inclusive of Russia, Turkey and Israel), where 3BP retains rights. The parties have also agreed to collaborate on a discovery program directed at three additional targets for radionuclide therapy, to which Clovis will have global rights.

Clovis currently plans to file an Investigational New Drug (IND) application for FAP-2286 in the second half of 2020.

Conference Call Details

Clovis will hold a conference call to discuss Q3 2019 results this morning, November 7, 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 (866) 393-4306, International participants (734) 385-2616, conference ID: 5045559.

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 (PDGFR α / 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 FAP-2286

FAP-2286 is a preclinical candidate under investigation as a peptide-targeted radionuclide therapy (PRT) and imaging agent targeting fibroblast activation protein alpha (FAP). FAP is highly expressed in many epithelial cancers, including more than 90 percent of breast, lung, colorectal and pancreatic carcinomas. Clovis is planning to file an investigational new drug application (IND) for FAP-2286 in the second half of 2020. Clovis will conduct the global clinical trials and holds U.S. and global rights, excluding Europe.

FAP-2286 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 enrollment in and conduct of 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 using changes in lesion appearance on imaging studies.

2 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 September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Revenues:				
Product revenue, net	\$ 37,603	\$ 22,757	\$ 103,699	\$ 65,037
Operating expenses:				
Cost of sales - product	8,134	4,766	21,984	13,262
Cost of sales - intangible asset amortization	1,212	771	3,549	1,851
Research and development	77,896	63,887	210,674	160,138
Selling, general and administrative	41,811	42,495	137,601	126,634
Acquired in-process research and development	9,440	-	9,440	-
Other operating expenses	5,539	-	5,539	-
Total expenses	144,032	111,919	388,787	301,885
Operating loss	(106,429)	(89,162)	(285,088)	(236,848)
Other income (expense):				
Interest expense	(5,278)	(3,376)	(12,684)	(9,592)
Foreign currency (loss) gain	(229)	151	(648)	(34)
Legal settlement loss	(1,750)	-	(26,750)	(27,975)
Gain on extinguishment of debt	18,480	-	18,480	-
Other income	781	2,536	5,081	5,419
Other income (expense), net	12,004	(689)	(16,521)	(32,182)
Loss before income taxes	(94,425)	(89,851)	(301,609)	(269,030)
Income tax benefit (expense)	350	(13)	686	280
Net loss	\$ (94,075)	\$ (89,864)	\$ (300,923)	\$ (268,750)
Basic and diluted net loss per common share	\$ (1.72)	\$ (1.71)	\$ (5.62)	\$ (5.18)
Basic and diluted weighted-average common shares outstanding	54,707	52,669	53,549	51,844

CONSOLIDATED BALANCE SHEET DATA
(Unaudited, in thousands)

	September 30, 2019	December 31, 2018
Cash and cash equivalents	\$ 201,481	\$ 221,876
Available-for-sale securities	152,622	298,270
Working capital	307,115	446,550
Total assets	716,892	863,560
Convertible senior notes	644,095	575,470
Common stock and additional paid-in capital	2,101,217	2,034,195
Total stockholders' (deficit) equity	(87,495)	146,469

Other Data
(Unaudited, in thousands)

	Nine Months Ended September 30, 2019	2018
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Net cash used in operating activities	(253,468)	(283,270)
Share Based Compensation Expense	41,748	37,715

Other Information
(\$ in millions)

Share-based compensation Q1 2019	13.6
Share-based compensation Q2 2019	14.1
Share-based compensation Q3 2019	14.0
Share-based compensation Q3 YTD 2019	41.7
Share-based compensation Q1 2018	11.9
Share-based compensation Q2 2018	14.9
Share-based compensation Q3 2018	10.9
Share-based compensation Q3 YTD 2018	37.7
Net cash used in operating activities Q1 2019	(98.5)
Net cash used in operating activities Q2 2019	(98.0)
Net cash used in operating activities Q3 2019	(57.0)
Net cash used in operating activities Q3 YTD 2019	(253.5)
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 Q3 2018	(72.5)
Net cash used in operating activities Q3 YTD 2018	(283.3)

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