



NEWS RELEASE

## Clovis Oncology Announces First Quarter 2020 Operating Results

5/5/2020

- \$42.6M in Rubraca® (rucaparib) global sales for Q1 2020; net product revenue up 8% over Q4 2019 and up 29% over Q1 2019
- Supplemental NDA for Rubraca in patients with BRCA1/2-mutant recurrent, metastatic castrate-resistant prostate cancer granted Priority Review by FDA with PDUFA date of May 15, 2020
- \$228.4M in cash, cash equivalents and available for sale securities at March 31, 2020; continue to anticipate cash runway into 2H 2021
- Improved balance sheet through convertible debt transactions in January, April and May 2020
- Lucitanib combination studies enrolling; initial data anticipated at medical meetings in 2H 2020
- Plan to submit IND for FAP-2286, a radiopharmaceutical therapy targeting FAP in 2H 2020

BOULDER, Colo.--(BUSINESS WIRE)-- **Clovis Oncology**, Inc. (NASDAQ:CLVS) reported financial results for the quarter ended March 31, 2020, 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 sales growth in the first quarter and believe that Rubraca is well-positioned as an oncology treatment option in the COVID-19 era," said Patrick J. Mahaffy, President and CEO of Clovis Oncology. "While we may see some impact on near-term revenues as oncology practices and patients adjust to the impact of this virus in the U.S. and Europe, it is obvious that cancer patients will continue to be diagnosed and treated given the evident risks in not actively managing their disease. We believe that Rubraca has significant advantages as a maintenance option in an environment in which physicians are trying to reduce patient visits to their clinics. Rubraca is an oral agent and is both delivered directly to and taken at home. Unlike observation, which on average requires a return to immunosuppressive chemotherapy after approximately five months, Rubraca has proven to extend progression-free survival by independent assessment on average nearly fourteen months. And finally, Rubraca only requires monthly routine monitoring. In addition to seeking to establish Rubraca as the maintenance treatment option of choice in recurrent ovarian cancer, we also look forward to the potential launch in the United

States of Rubraca in BRCA1/2-mutant recurrent, metastatic castrate-resistant prostate cancer.”

## First Quarter 2020 Financial Results

Clovis reported product revenue for Rubraca of \$42.6 million for the first quarter of 2020, which included U.S. product revenue of \$39.3 million and ex-U.S. product revenue of \$3.3 million. This compares to 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. This represents a 29 percent increase year over year and 8 percent increase sequentially compared to Q4 2019 product revenue of \$39.3 million. U.S. product revenues were up nine percent over the \$36.1 million reported in Q4 2019 and ex-U.S. product revenue increased two percent from \$3.2 million reported in Q4 2019.

Clovis had \$228.4 million in cash, cash equivalents and available-for-sale securities as of March 31, 2020.

In January 2020, the Company repurchased \$123.4 million aggregate principal amount of its 4.50% convertible senior notes due 2024 that were initially issued in August 2019. In April 2020, the Company exchanged approximately \$36.05 million in aggregate principal amount of its 4.50% convertible senior notes due 2024 for approximately \$32.77 million in aggregate principal of 2021 notes. In May 2020, a holder of the 4.50% convertible senior notes due 2024 converted \$24.3 million par value of notes into approximately 3.3 million shares of common stock per the standard terms of the indenture. Following these transactions, approximately \$64.42 million aggregate principal amount of these 2021 notes remain outstanding and approximately \$150.63 million aggregate principal amount of these 2024 notes remain outstanding. Additionally, the Company has \$300 million aggregate principal amount outstanding of its 1.25% convertible senior notes due 2025. As a result of the transactions noted above, the Company has reduced its total outstanding convertible debt by \$145.1 million in outstanding principal amount from December 31, 2019 through May 5, 2020.

As of March 31, 2020, the Company had drawn approximately \$50 million under the TPG ATHENA clinical trial financing and had up to \$125 million available to draw under the 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 \$64.42 million aggregate principal amount of the 2.50% convertible notes, at their maturity in September 2021. While we have not yet seen a material impact on our revenues, the effects of COVID-19 on future sales are difficult to assess or predict.

Net cash used in operating activities was \$82.5 million for the first quarter of 2020, compared with \$98.5 million for the first quarter of 2019. Borrowings under the TPG ATHENA financing provided \$15.6 million in Q1 2020, reducing net cash utilized in operating activities to \$66.9 million in Q1 2020. Net cash used in operating activities for Q1 2020 included product supply costs of \$12.4 million. We expect product supply costs will be significantly reduced from this first quarter level for the remainder of 2020 and at least the first half of 2021.

Clovis reported a net loss for the first quarter of 2020 of \$99.3 million, or (\$1.39) per share, compared to the net loss for the first quarter of 2019 which was \$86.4 million, or (\$1.63) per share. Net loss for the first quarter of 2020 included share-based compensation expense of \$13.0 million, compared to \$13.6 million for the first quarter of 2019.

Research and development expenses totaled \$68.2 million for the first quarter of 2020, compared to \$62.0 million for the first quarter of 2019. Research and development expenses increased during the three months ended March 31, 2020 compared to the same period in the prior year primarily due to higher research and development costs for Rubraca. We expect research and development expenses to be lower in the full year 2021 compared to full year 2020.

Selling, general and administrative expenses totaled \$42.6 million for the first quarter of 2020, compared to \$47.8 million for the comparable period in 2019. Selling, general and administrative expenses decreased during the three months ended March 31, 2020 compared to the same period in the prior year primarily due to decreased commercialization expenses for Rubraca in the U.S. and Europe. We expect savings in selling, general and administrative expenses as a result of the COVID-19 situation globally.

## European Launch of Rubraca in Ovarian Cancer

In January 2019, the European Commission granted a variation to the marketing authorization for Rubraca to include 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. Following successful reimbursement negotiations, Clovis has launched Rubraca in each of Germany, United Kingdom, Italy, France and Spain, and over time expects to launch in additional smaller European markets.

## U.S. Supplemental New Drug Application for Rubraca in BRCA1/2-mutant Metastatic Castration-resistant Prostate Cancer (mCRPC)

In January 2020, Clovis announced that the FDA accepted the Company's supplemental New Drug Application (sNDA) for Rubraca as a monotherapy treatment of adult patients with BRCA1/2-mutant recurrent, metastatic castrate-resistant prostate cancer and granted priority review status to the application with a Prescription Drug

User Fee Act (PDUFA) date of May 15, 2020. The sNDA filing, submitted in November 2019, was based on data from the TRITON clinical program in advanced prostate cancer. The Company is actively preparing for the launch of Rubraca in prostate cancer in the U.S. to commence upon receipt of FDA approval. Given the ongoing quarantine in the U.S., this product launch will be among the first virtual-only launches in oncology.

## Lucitanib Combination Studies Underway

Two Clovis-sponsored early Phase 1b/2 lucitanib combination studies are currently underway: LIO-1, evaluating lucitanib and nivolumab in combination in advanced solid tumors (Phase 1b) and gynecologic cancers (Phase 2); and lucitanib in combination with rucaparib in advanced solid tumors (Phase 1b) and ovarian cancer (Phase 2) as an arm of the SEASTAR study. Clovis anticipates submitting abstracts for presentations at medical meetings in the Fall of 2020.

## Conference Call Details

Clovis will hold a conference call to discuss Q1 2020 results this afternoon, May 5, at 4:30pm ET. The conference call will be simultaneously webcast on the Clovis Oncology web site [www.clovisoncology.com](http://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: 1140127.

## 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 Europe, 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. Rubraca is also approved in Europe 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 Europe.

## 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 $\alpha$ / $\beta$ ) 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 discovered by 3B Pharmaceuticals 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 submit 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](http://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 our future cash position, our expectations regarding the impact of COVID-19 on our business operations and results, including future revenues, supply and distribution of our clinical trial supplies and commercial product supplies, our expectations regarding our ability to maintain the enrollment and conduct of our clinical trials and other development activities, expectations concerning future regulatory activities including the U.S. Food and Drug Administration's ("FDA") target PDUFA date for, and potential approval of, our sNDA for Rubraca in patients with BRCA1/2-mutant recurrent, metastatic castrate-resistant prostate cancer, our plans for commercial launch in expanded indications in the United States, 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 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 impacts of the COVID-19 pandemic and disruption related to efforts to mitigate its spread on our business, results of operations or financial condition, including impacts on the vendors or distribution channels in our supply chain, impacts on our contract manufacturers' ability to continue to manufacture our products, impacts on our ability to continue our development activities, impacts on the conduct of our clinical trials, including with respect to enrollment rates, availability of investigators and clinical trial sites or monitoring of data and impact on the ability and timing of our field personnel to conduct their activities with health care providers, the uncertainties inherent in the effect our future revenues or expenses may have on our cash position, 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.

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

	Three Months Ended March 31,	
	2020	2019
Revenues:		
Product revenue	\$ 42,564	\$ 33,118
Operating expenses:		
Cost of sales - product	9,096	7,405
Cost of sales - intangible asset amortization	1,212	1,120
Research and development	68,221	62,031
Selling, general and administrative	42,598	47,761
Other operating expenses	3,449	-
Total expenses	124,576	118,317
Operating loss	(82,012)	(85,199)
Other income (expense):		
Interest expense	(9,561)	(3,590)
Foreign currency loss	(877)	(192)
Loss on convertible senior notes conversion	(7,791)	-
Other income	841	2,400
Other income (expense), net	(17,388)	(1,382)
Loss before income taxes	(99,400)	(86,581)
Income tax benefit	68	160
Net loss	\$ (99,332)	\$ (86,421)
Basic and diluted net loss per common share	\$ (1.39)	\$ (1.63)
Basic and diluted weighted-average common shares outstanding	71,662	52,891

CONSOLIDATED BALANCE SHEET DATA  
(Unaudited, in thousands)

	March 31, 2020	December 31, 2019
Cash and cash equivalents	\$ 163,309	\$ 161,833
Available-for-sale securities	65,051	134,826
Working capital	179,122	233,384
Total assets	601,793	669,604
Convertible senior notes	524,905	644,751
Common stock and additional paid-in capital	2,260,744	2,114,123
Total stockholders' deficit	(126,994)	(174,257)

Other Data  
(Unaudited, in thousands)

Three Months Ended March 31,

	2020	2019
Net cash used in operating activities	(82,494)	(98,451)
Share Based Compensation Expense	12,961	13,640

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Source: Clovis Oncology, Inc.