



NEWS RELEASE

Clovis Oncology Announces First Quarter 2021 Operating Results

5/5/2021

- \$38.1M in Rubraca® (rucaparib) global net product revenues for Q1 2021, down 11% vs. Q1 2020, due to continued headwinds from COVID-19 in the US and Europe
- Maintained US market share as US PARP inhibitor market impacted by COVID-19
- Imaging and treatment INDs cleared by FDA for FAP-2286, a novel peptide-targeted radionuclide therapy (PTRT)
- Phase 1/2 LuMIERE study of FAP-2286 expected to open for enrollment this quarter
- Top-line data from Phase 3 ATHENA trial of Rubraca as first-line maintenance treatment for ovarian cancer monotherapy anticipated 2H 2021
- \$190.9M in cash and cash equivalents and \$61.4M in available funding under the ATHENA financing at March 31, 2021, anticipated to fund the Company's operating plan into early 2023 based on current revenue and expense forecasts
- \$28.1M reduction in R&D and SG&A expense and 25% reduction in net cash used in operating activities compared to Q1 2020

BOULDER, Colo.--(BUSINESS WIRE)-- **Clovis Oncology**, Inc. (NASDAQ:CLVS) reported financial results for the quarter ended March 31, 2021, and provided an update on the Company's **clinical development programs** and regulatory and commercial outlook for the rest of the year.

"The second quarter of 2021 marks an important moment in our commitment to targeted radionuclide therapies, as the FDA clearance of our INDs for FAP-2286 enables us to initiate the Phase 1 portion of the LuMIERE study this quarter as planned. We are increasingly enthusiastic about FAP-2286 and its potential to treat patients with solid tumors, and about targeted radiotherapeutics as a class," said Patrick J. Mahaffy, President and CEO of Clovis Oncology. "While continuing headwinds from COVID-19 impacted Rubraca sales this quarter, we believe this effect will lessen over the course of this year. Importantly, since each approved PARP inhibitor faced some impact from COVID-19 in the US market in Q1 2021 compared to Q4 2020, we believe we maintained market share in the US.

Finally, we are not far from top-line ATHENA monotherapy data as a front-line maintenance treatment for women with advanced ovarian cancer, expected in the second half of this year, which will be the most important indication for Rubraca.”

First Quarter 2021 Financial Results

Clovis reported global net product revenues for Rubraca of \$38.1 million for Q1 2021, which included US product revenues of \$31.7 million and ex-US product revenues of \$6.4 million, respectively. This represents an 11% decrease year-over-year, compared to Q1 2020 net product revenues of \$42.6 million, which included US net product revenues of \$39.3 million and ex-US net product revenues of \$3.3 million. The decrease was primarily due to fewer diagnoses and fewer patient starts, substantially due to the ongoing COVID-19 pandemic. In addition, first quarter 2020 was the Company’s strongest quarter of US Rubraca sales to date, and the COVID-19 pandemic had limited, if any, effect on Q1 2020 net revenues.

Research and development expenses totaled \$52.8 million for Q1 2021, down 23% compared to \$68.2 million for the comparable period in 2020, due primarily to lower spending on Rubraca clinical trials. As previously discussed, the Company expects research and development expenses to be lower in the full year 2021 compared to 2020.

Selling, general and administrative expenses totaled \$29.9 million for Q1 2021, down 30% compared to \$42.6 million for the comparable period in 2020, due to the COVID-19 situation globally and overall cost reduction efforts. Clovis continues to expect selling, general and administrative expenses to decrease in the full year 2021 compared to 2020.

Clovis reported a net loss for Q1 2021 of \$66.3 million, or (\$0.64) per share, compared to a net loss for Q1 2020 of \$99.3 million, or (\$1.39) per share. Net loss for Q1 2021 included share-based compensation expense of \$4.0 million, compared to \$13.0 million for the comparable period of 2020.

Clovis had \$190.9 million in cash and cash equivalents as of March 31, 2021, which together with the ATHENA clinical trial financing, is expected to fund the Company’s operating plan into early 2023 based on current revenue and expense forecasts.

As of March 31, 2021, the Company had drawn \$113.6 million under the Sixth Street Partners, LLC (SSP) ATHENA clinical trial financing and had up to \$61.4 million available to draw under the agreement to fund the expenses of the ATHENA trial.

Net cash used in operating activities was \$61.9 million for Q1 2021, down from \$82.5 million reported in Q1 2020. Cash burn in Q1 2021 was \$48.1 million, down 28% from \$66.9 million in Q1 2020. We expect this trend of lower

cash burn to continue in 2021.

Clovis Oncology Pipeline Highlights

Anticipated Rubraca Pipeline Events in 2021

Top-line data from the ATHENA Phase 3 study in first-line maintenance treatment ovarian cancer setting evaluating Rubraca monotherapy versus placebo are expected in the second-half of 2021, contingent upon the occurrence of the protocol-specified progression-free survival (PFS) events. Data from the combination arm of Rubraca plus Opdivo® (nivolumab) versus Rubraca monotherapy are expected a year or more later.

LODESTAR, the Company's Phase 2 trial of Rubraca in patients with solid tumors with deleterious mutations in homologous recombination repair (HRR) genes is currently enrolling. This study may be registration-enabling, with a potential regulatory filing in 1H 2022.

LuMIERE Phase 1/2 Study of FAP-2286 Expected to Begin 1H 2021

FAP-2286 is Clovis Oncology's peptide-targeted radionuclide therapy (PRTT) and imaging agent targeting fibroblast activation protein (FAP) and is the lead candidate in the Company's PRTT development program. With FDA clearance of each of the treatment and imaging IND applications for FAP-2286, Clovis expects to open for enrollment the Phase 1/2 LuMIERE clinical study this quarter. The Phase 1 portion of the LuMIERE study will evaluate the safety of the FAP-targeting investigational therapeutic agent and identify the recommended Phase 2 dose and schedule of lutetium-177 labeled FAP-2286 (¹⁷⁷Lu-FAP-2286). FAP-2286 labeled with gallium-68 (⁶⁸Ga-FAP-2286) will be utilized as an investigational imaging agent to identify patients with FAP-positive tumors appropriate for treatment with the therapeutic agent. Once the Phase 2 dose is determined, Phase 2 expansion cohorts are planned in multiple tumor types.

Interim LIO-1 Data of Lucitanib and Opdivo in Combination Expected in 2021

Clovis Oncology's Phase 1b/2 LIO-1 study is evaluating the combination of lucitanib and Opdivo in gynecologic cancers, and the Phase 2 portion is enrolling patients into four expansion cohorts: non-clear cell ovarian; non-clear cell endometrial; cervical; and clear-cell ovarian and endometrial cancers. Interim data from the non-clear-cell ovarian cancer expansion cohort have been accepted as a poster presentation at ASCO in early June, and while evidence of clinical activity has been observed, Clovis does not believe that the efficacy data support further development in non-clear-cell ovarian cancer. Enrollment continues in the three other expansion cohorts, and the Company continues to plan to submit an abstract to a medical meeting later this year describing the interim endometrial cohort data.

Conference Call Details

Clovis will hold a conference call to discuss Q1 2021 results this morning, May 5, at 8:30am ET. The conference call will be simultaneously webcast on the Clovis Oncology website 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: 3219208.

About Rubraca (rucaparib)

Rubraca is an oral, small molecule inhibitor of PARP1, PARP2 and PARP3 being developed in multiple tumor types, including ovarian and prostate cancers, as monotherapy and in combination with other anti-cancer agents. Exploratory studies in other tumor types are also underway. 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. Additionally, Rubraca is approved in the US for the treatment of adult patients with a deleterious BRCA mutation (germline and/or somatic)-associated metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor-directed therapy and a taxane-based chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for Rubraca. This indication is approved under accelerated approval based on objective response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. The TRITON3 clinical trial is expected to serve as the confirmatory study for the Rubraca accelerated approval in mCRPC.

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 the US and Europe.

About FAP-2286

FAP-2286 is a clinical candidate under investigation as a peptide-targeted radionuclide therapy (PTRT) and imaging agent targeting fibroblast activation protein (FAP). FAP-2286 consists of two functional elements; a targeting peptide that binds to FAP and a site that can be used to attach radioactive isotopes for imaging and therapeutic use. FAP is highly expressed on cancer-associated fibroblasts (CAFs) in many epithelial cancers, including more than 90% of breast, lung, colorectal, and pancreatic carcinomas.ⁱ Clovis holds US and global rights for FAP-2286 excluding Europe, Russia, Turkey, and Israel.

FAP-2286 is an unlicensed medical product.

About Targeted Radionuclide Therapy

Targeted radionuclide therapy is an emerging class of cancer therapeutics, which seeks to deliver radiation directly to the tumor while minimizing delivery of radiation to normal tissue. Targeted radionuclides are created by linking radioactive isotopes, also known as radionuclides, to targeting molecules (e.g., peptides, antibodies, small molecules) that can bind specifically to tumor cells or other cells in the tumor environment. Based on the radioactive isotope selected, the resulting agent can be used to image and/or treat certain types of cancer. Agents that can be adapted for both therapeutic and imaging use are known as “theranostics.” Clovis is developing a pipeline of novel, targeted radiotherapies for cancer treatment and imaging, including its lead candidate, FAP-2286, an investigational peptide-targeted radionuclide therapeutic (PTRT) and imaging agent, as well as three additional discovery-stage compounds.

About Lucitanib

Lucitanib is an investigational angiogenesis inhibitor which inhibits 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 may reverse this immunosuppression and augment response to immunotherapy. Clovis holds global rights for lucitanib excluding China.

Lucitanib is an unlicensed medical product.

About Clovis Oncology

Clovis Oncology, Inc. is a biopharmaceutical company focused on acquiring, developing, and commercializing innovative anti-cancer agents in the US, 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 US 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, 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, 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 Sixth Street Partners, LLC. 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 timing and extent of recovery from the impact of COVID-19, 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.

i Rettig WJ et al. Regulation and Heteromeric Structure of the Fibroblast Activation Protein in Normal and Transformed Cells of Mesenchymal and Neuroectodermal Origin. Cancer Res. 1993;53:3327–3335.

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

	Three Months Ended March 31,	
	2021	2020
Revenues:		
Product revenue	\$ 38,053	\$ 42,564
Operating expenses:		
Cost of sales - product	8,268	9,096
Cost of sales - intangible asset amortization	1,343	1,212
Research and development	52,805	68,221
Selling, general and administrative	29,941	42,598
Other operating expenses	3,707	3,449
Total expenses	96,064	124,576
Operating loss	(58,011)	(82,012)
Other income (expense):		
Interest expense	(8,037)	(9,561)
Foreign currency loss	(546)	(877)
Loss on convertible senior notes conversion	-	(7,791)
Other income	183	841
Other income (expense), net	(8,400)	(17,388)
Loss before income taxes	(66,411)	(99,400)
Income tax benefit	134	68
Net loss	\$ (66,277)	\$ (99,332)
Basic and diluted net loss per common share	\$ (0.64)	\$ (1.39)

Basic and diluted weighted-average common shares

104,246

71,662

CONSOLIDATED BALANCE SHEET DATA
(In thousands)

	March 31, 2021 (Unaudited)		December 31, 2020	
Cash and cash equivalents	\$	190,922	\$	240,229
Working capital		79,277		125,901
Total assets		548,838		605,554
Convertible senior notes		499,625		499,044
Common stock and additional paid-in capital		2,502,349		2,498,283
Total stockholders' deficit		(221,039)		(158,748)

Other Data
(Unaudited, in thousands)

	Three Months Ended March 31,		
	2021	2020	
Net cash used in operating activities	\$	(61,890)	(82,494)
Share Based Compensation Expense		4,039	12,961

RECONCILIATION OF NET CASH USED IN OPERATING
ACTIVITIES TO CASH BURN
(Unaudited, in thousands)

	Three Months Ended March 31,		
	2021	2020	
Net cash used in operating activities	\$	(61,890)	(82,494)
Adjustments:			
Proceeds from borrowings under financing agreement		13,802	15,592
Cash burn	\$	(48,088)	(66,902)
Net cash (used in) provided by investing activities	\$	(118)	69,807
Net cash provided by financing activities	\$	13,376	14,644

To supplement our financial statements prepared in accordance with U. S. GAAP, we monitor and consider cash burn, which is a non-U.S. GAAP financial measure. This non-U.S. GAAP financial measure is not based on any standardized methodology prescribed by U.S. GAAP and is not necessarily comparable to similarly-titled measures presented by other companies. We define cash burn as net cash used in operating activities less proceeds from borrowings under financing agreement with Sixth Street specifically related to our Phase 3 ATHENA trial. We believe cash burn to be a liquidity measure that provides useful information to management and investors about the amount of cash consumed by the operations of the business including proceeds from borrowings under the Sixth Street financing agreement, which specifically offsets the costs of our ATHENA trial. A limitation of using this non-U.S. GAAP measure is that cash burn does not represent the total change in cash and cash equivalents for the period because it excludes all other cash provided by or used for other investing and financing activities. We account for this limitation by providing information about our investing and financing activities in the statements of cash flows in our financial statements and by presenting cash flows from investing and financing activities in our reconciliation of cash burn. In addition, it is important to note that other companies, including companies in our industry, may not use cash burn, may calculate cash burn in a different manner than we do or may use other financial measures to evaluate their performance, all of which could reduce the usefulness of cash burn as a comparative measure. Because of these limitations, cash burn should not be considered in isolation from, or as a substitute for, financial information prepared in accordance with U.S. GAAP.

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