NEWS RELEASE

Clovis Oncology Announces Third Quarter 2021 Operating Results

11/3/2021

- $37.9M in Rubraca® (rucaparib) global net product revenues for Q3 2021, up 3% over Q2 2021 and down 2% from Q3 2020
- Three top-line Phase 3 data read-outs for Rubraca expected in 2022 with potential to address larger ovarian and prostate cancerpatient populations in earlier lines of therapy
- Phase 1 LuMIERE study of targeted radiotherapy candidate FAP-2286 ongoing; initial Phase 1 data expected at medical meeting in 2022, as well as initiation of Phase 2 expansion cohorts in multiple tumor types
- Retired final $64.4M in principal amount of 2021 notes and raised net proceeds of $41.5M through ATM equity offering program in Q3 2021, complementing ongoing focus on cost control
- $171.9M in cash and cash equivalents and $37.5M in available funding under the ATHENA financing at September 30, 2021
- Reduction in R&D and SG&A expense of $23.1M, or 23%, and reduction in net cash used in operating activities of $8.3M, or 15%, each as compared to Q3 2020

BOULDER, Colo.--(BUSINESS WIRE)-- **Clovis Oncology**, Inc. (NASDAQ:CLVS) reported financial results for the quarter ended September 30, 2021, and provided an update on the Company's **clinical development programs** and regulatory and commercial outlook.

"While COVID-19 continues to impact our revenues, as fewer patients have been diagnosed and treated for ovarian cancer during the pandemic, it has not affected our development programs. We remain on track for an eventful 2022, with three data readouts from Phase 3 ATHENA and TRITON3 studies of Rubraca with label expansion potential, as well as initial data from the ongoing Phase 1 LuMIERE study of our first targeted radiotherapy candidate FAP-2286 anticipated during 2022," said Patrick J. Mahaffy, President and CEO of Clovis Oncology. "With the additional capital raised in the quarter and recent repayment of the remaining 2021 notes, we have made further progress on improving our balance sheet and remain focused on our three core strategies: expand the Rubraca label to drive revenue growth, emerge as a leader in targeted radionuclide therapy, and achieve long-term

financial stability."

Third Quarter 2021 Financial Results

Clovis reported global net product revenues for Rubraca of $37.9 million for Q3 2021, which included US product revenues of $28.7 million and ex-US product revenues of $9.2 million, respectively. This represents a sequential 3% increase over Q2 2021 and a 2% decrease year-over-year, compared to Q3 2020 net product revenues of $38.8 million, which included US net product revenues of $33.9 million and ex-US net product revenues of $4.9 million. The decrease in year-over-year revenues was primarily due to fewer ovarian cancer diagnoses and fewer patients treated in the US related to the ongoing impact of COVID-19.

Clovis reported net product revenue for Rubraca of $112.8 million for the nine months ended September 30, 2021, which included US product revenue of $88.1 million and ex-US product revenue of $24.7 million, compared to net product revenue for same period in 2020 of $121.2 million, which included US net product revenue of $109.8 million and ex-US net product revenue of $11.4 million.

Research and development expenses totaled $46.2 million for Q3 2021, down 27% compared to $62.9 million for the comparable period in 2020, due primarily to lower spending on Rubraca clinical trials. For the nine months ended September 30, 2021, research and development expenses totaled $144.8 million, down 28% compared to $201.0 million for the comparable period in 2020. 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 $32.2 million for Q3 2021, down 17% compared to $38.6 million for the comparable period in 2020, due to overall cost reduction efforts. For the nine months ended September 30, 2021, selling, general and administrative expenses totaled $95.1 million, down 23% compared to $123.1 million for the comparable period in 2020. 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 Q3 2021 of $67.4 million, or ($0.56) per share, compared to a net loss for Q3 2020 of $78.7 million, or ($0.89) per share. Net loss for Q3 2021 included share-based compensation expense of $7.0 million, compared to $12.5 million for the comparable period of 2020.

Clovis had $171.9 million in cash and cash equivalents as of September 30, 2021. During Q3 2021, the Company established an "at-the-market" equity offering program (ATM) with the capacity to issue up to $125 million of shares of common stock. During Q3, the Company raised $41.5 million in net proceeds through this ATM. Clovis also paid off in full at maturity, the remaining $64.4 million in principal amount outstanding of its 2.50% convertible senior notes due 2021. The Company's next convertible debt maturity is August 1, 2024 and has a conversion price of

$7.29 for a portion, and a conversion price of $6.24 for the remainder.

As of September 30, 2021, the Company had drawn $137.5 million under the Sixth Street Partners, LLC (SSP) ATHENA clinical trial financing and had up to $37.5 million available to draw under the agreement to fund the expenses of the ATHENA trial.

Net cash used in operating activities was $46.1 million for Q3 2021, down 15% from the $54.3 million reported in Q3 2020. Net cash used in operating activities for the first nine months of 2021 was $154.7 million, down 21% from the same period in 2020.

Cash burn in Q3 2021 was $35.5 million, down 6% from $37.7 million in Q3 2020. Cash burn for the first nine months of 2021 was $117.0 million, down 24% from $154.7 million in the first nine months of 2020.

Clovis Oncology Pipeline Highlights

Three Anticipated Rubraca Phase 3 studies on Track for 2022 Readouts

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 first quarter of 2022 based on event-based projections. Data from the combination arm of Rubraca plus Opdivo® (nivolumab) versus Rubraca monotherapy are expected in the second half of 2022 based on protocol-defined assumptions.

Top-line data from the TRITON3 trial, which is expected to serve as the confirmatory study for Rubraca's approval in metastatic castration-resistant prostate cancer (mCRPC) as well as a potential second-line label expansion, are expected in the second quarter of 2022. TRITON3 is a Phase 3 study evaluating Rubraca versus physician's choice of chemotherapy or second-line androgen deprivation therapy in patients with mCRPC with BRCA and ATM mutations.

The three anticipated data readouts, ATHENA monotherapy, ATHENA combination and TRITON3, provide the potential to reach larger patient populations in earlier lines of therapy for ovarian and prostate cancers, in which Rubraca is currently approved in later-line indications. The timing for each full data release is contingent upon the occurrence of the protocol-specified progression-free survival (PFS) events.

LuMIERE Phase 1/2 Study of FAP-2286 Enrolling Patients with FAP-Positive Solid Tumors into Phase 1; Initial Phase 1 LuMIERE Data Expected in 2022

FAP-2286 is the first peptide-targeted radionuclide therapy (PTRT) and imaging agent targeting fibroblast activation protein (FAP) to enter clinical development and is the lead candidate in Clovis Oncology's TRT development

program. The ongoing Phase 1 portion of the LuMIERE study, for which enrollment in the second dose cohort is expected to initiate in Q4 2021, is evaluating the safety of the FAP-targeting investigational therapeutic agent and will 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 used as an investigational imaging agent to identify patients with FAP-positive tumors appropriate for treatment in LuMIERE. The first presentations of Phase 1 data from LuMIERE are expected at medical meetings in 2022. Once the Phase 2 dose is determined, Phase 2 expansion cohorts are planned in multiple tumor types and are expected to initiate in 2022.

Nonclinical data evaluating FAP expression across a variety of solid tumor types were presented at AACR-NCI-EORTC in October. High FAP expression was observed in multiple indications, including pancreatic ductal adenocarcinoma, salivary gland, mesothelioma, colon, bladder, sarcoma, squamous NSCLC, and head and neck cancers as well as in cancers of unknown primary. In these tumor types, high FAP expression was detected in both primary and metastatic tumor samples and was independent of tumor stage or grade. The analysis also demonstrated that in most tumor types, FAP expression was predominantly localized to cancer-associated fibroblasts (CAFs) surrounding the tumor cells and integrated into the tumor microenvironment. In addition, in cancers of mesenchymal origin including sarcoma and mesothelioma, expression was observed in tumor cells in addition to CAFs. These data support the investigation of FAP-2286 in multiple tumor types in the planned Phase 2 expansion cohorts of LuMIERE. Additional presentations of nonclinical data are anticipated at medical meetings over the next few quarters.

In addition, Clovis and ITM Isotope Technologies Munich SE recently announced the signing of a clinical supply agreement that provides Clovis with ITM's therapeutic radioisotope no-carrier-added lutetium-177 (n.c.a. 177Lu), EndolucinBeta®, for use in the clinical development of FAP-2286 for the next five years.

For more information about FAP-2286, targeted radionuclide therapy (TRT), or Clovis' TRT development program, **click here**.

Conference Call Details

Clovis will hold a conference call this morning, November 3, at 8:30am ET, to discuss Q3 2021 results and provide an update on the Company's clinical development programs and regulatory and commercial outlook. The conference call will be simultaneously webcast on the Clovis Oncology website at **clovisoncology.com**, and archived for future review. Dial-in numbers for the conference call are as follows: US participants (888) 440-4615, International participants (646) 960-0682, conference ID: 2259685.

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. High FAP expression has been shown in pancreatic ductal adenocarcinoma, salivary gland, mesothelioma, colon, bladder, sarcoma, squamous non-small cell lung, squamous head and neck cancers, and cancers of unknown primary. High FAP expression was detected in both primary and metastatic tumor samples and was independent of tumor stage or grade. 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 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 made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. 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 those 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.

	2021	2020	2021	2020
Revenues:				
Product revenue	$ 37,916	$ 38,772	$ 112,789	$ 121,223
Operating expenses:				
Cost of sales - product	8,506	8,438	25,068	26,654
Cost of sales - intangible asset amortization	1,343	1,343	4,028	3,834
Research and development	46,222	62,902	144,786	201,000
Selling, general and administrative	32,196	38,636	95,055	123,136
Acquired in-process research and development	3,272	-	5,477	-
Other operating expenses	3,841	-	11,431	3,805
Total expenses	95,380	111,319	285,845	358,429
Operating loss	(57,464)	(72,547)	(173,056)	(237,206)
Other income (expense):				
Interest expense	(8,786)	(6,859)	(25,593)	(23,160)
Foreign currency (loss) gain	(1,248)	633	(2,001)	(102)
Loss on convertible notes conversion	-	-	-	(7,791)
Loss on extinguishment of debt	-	-	-	(3,277)
Other income	101	79	392	1,160
Other income (expense), net	(9,933)	(6,147)	(27,202)	(33,170)
Loss before income taxes	(67,397)	(78,694)	(200,258)	(270,376)
Income tax (expense) benefit	(13)	18	125	122
Net loss	$ (67,410)	$ (78,676)	$ (200,133)	$ (270,254)
Basic and diluted net loss per common share	$ (0.56)	$ (0.89)	$ (1.80)	$ (3.37)
Basic and diluted weighted-average common shares	121,217	88,255	111,377	80,153

CONSOLIDATED BALANCE SHEET DATA
(Unaudited, in thousands)

	September 30, 2021	Dec 31, 2020
Cash and cash equivalents	$ 171,949	$ 240,229
Working capital	117,973	125,901
Total assets	507,997	605,554
Convertible senior notes	436,263	499,044
Common stock and additional paid-in capital	2,631,356	2,498,283
Total stockholders' deficit	(225,461)	(158,748)

Other Data
(Unaudited, in thousands)

	Nine Months Ended September 30,	
	2021	2020
Net cash used in operating activities	$ (154,714)	$ (196,675)
Share Based Compensation Expense	$ 18,402	$ 38,765

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Net cash used in operating activities	$ (46,069)	$ (54,324)	$ (154,714)	$ (196,675)
Adjustments:				
Acquired in-process research and development - milestone payment	-	-	-	(8,000)
Proceeds from borrowings under financing agreement	10,576	16,641	37,730	49,963
Cash burn	$ (35,493)	$ (37,683)	$ (116,984)	$ (154,712)

Net cash (used in) provided by investing activities	$ (89)	$ (19)	$ (243)	$ 126,588
Net cash (used in) provided by financing activities	$ (12,326)	$ 16,157	$ 86,990	$ 131,808

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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Breanna Burkart
(303) 625-5023
bburkart@clovisoncology.com

Anna Sussman
(303) 625-5022
asussman@clovisoncology.com

Source: Clovis Oncology, Inc.