Clovis Oncology Announces Q1 2016 Operating Results and Corporate Update

May 5, 2016 4:06 PM ET

- *Rucaparib rolling NDA submission initiated for treatment of patients with advanced ovarian cancer with deleterious BRCA mutated tumors and expected to complete Q2 2016*
- *Rucaparib MAA submission planned Q4 2016*
- *Clovis preparing for potential U.S. commercial launch of rucaparib with existing commercial infrastructure in Q4 2016 or Q1 2017*
- *ARIEL3 pivotal rucaparib maintenance study target enrollment completed*
- *Clovis entered into a clinical trial collaboration to evaluate a novel combination therapy of atezolizumab (MPDL3280A; anti-PDL1) and rucaparib for the treatment of gynecological cancers*
- *Complete Response Letter (CRL) for rociletinib anticipated on or before June 28 PDUFA date*
- *Clovis has withdrawn its Marketing Authorization Application of rociletinib with European regulatory authorities*
- *Clovis has terminated enrollment in all ongoing sponsored studies of rociletinib, including TIGER-3*
- *$445.5 million in cash, cash equivalents and available-for-sale securities at the end of Q1 2016; Company anticipates ending 2016 with approximately $220-$235M in cash, cash equivalents and available-for-sale securities*
- *Clovis has sufficient cash to fund operations into 2018*

BOULDER, Colo.--(BUSINESS WIRE)--May 5, 2016-- Clovis Oncology, Inc. (NASDAQ:CLVS) reported financial results for its quarter ended March 31, 2016, and provided an update on the Company's clinical development programs and regulatory outlook for the remainder of 2016.

"We are very disappointed in the outcome for rociletinib, as there is a need for additional options for this difficult to treat disease," said Patrick J. Mahaffy, President and CEO of Clovis Oncology. "Our focus moving forward is clear: prioritize rucaparib development activity and prepare for its potential U.S. launch, and manage our existing cash into 2018."

First Quarter 2016 Financial Results

Clovis had $445.5 million in cash, cash equivalents and available-for-sale securities as of March 31, 2016. Cash used in operating activities was $83.7 million for the first quarter of 2016, compared with $48.4 million in the first quarter of 2015. Clovis had approximately 38.4 million outstanding shares of common stock as of March 31, 2016.

Clovis reported a net loss for the first quarter of 2016 of $83.4 million, or ($2.17) per share, compared to a net loss of $63.1 million, or ($1.86) per share, for the first quarter of 2015. Net loss for the first quarter of 2016 included share-based compensation expense of $11.0 million compared to $8.7 million for the first quarter of 2015.

Research and development expenses totaled $74.6 million for the first quarter of 2016, compared to $56.8 million for the first quarter 2015. The year-over-year increase in expenses is due to the significantly expanded clinical development activities for rucaparib, increased commercial product planning costs and increased personnel-related expenses associated with the hiring of additional staff including the U.S. sales force to support the Company's expanded activities, partially offset by lower expenses related to clinical development activities for rociletinib.

General and administrative expenses totaled $9.8 million for the first quarter of 2016, compared to $6.8 million for the first quarter 2015. The increase year over year is primarily due to higher legal expense, consulting fees and personnel costs for employees engaged in general and administrative activities.

The Company expects cash used in operating activities for 2016 will total approximately $294 - $309 million, and to end the year with approximately $220 - $235 million in cash, cash equivalents and available-for-sale securities. Clovis anticipates being able to continue to fund operations into 2018 from currently available cash, cash equivalents and available-for-sale securities.

2016 Key Milestones and Objectives

Highlights of planned or completed objectives for each product follow:

Rucaparib

During the second quarter of 2016, Clovis commenced the submission of its rolling New Drug Application (NDA) regulatory filing to the U.S. Food and Drug Administration (FDA) for rucaparib for the monotherapy treatment of patients with advanced ovarian cancer with deleterious BRCA-mutated tumors (inclusive of both germline and somatic BRCA mutations) previously treated with multiple prior therapies. Rucaparib was granted Breakthrough Therapy designation by the FDA in April 2015. Clovis agreed with the FDA that the submission would be a rolling NDA and has filed the first component for potential accelerated approval of rucaparib in the U.S. The rolling NDA allows completed portions of an NDA to be submitted and reviewed by the FDA on an ongoing basis. The Company intends to complete the NDA submission by the end of the second quarter of 2016.

Foundation Medicine, Clovis' companion diagnostic partner, intends to file a Premarket approval application (PMA) of its diagnostic assay designed to identify both germline and somatic BRCA mutations with the FDA. The timing of the submission is expected to allow for regulatory approval of the companion diagnostic at substantially the same time that rucaparib would be approved.

In addition, the Company intends to submit its Marketing Authorization Application (MAA) for rucaparib to the European Medicines Agency for a comparable ovarian cancer treatment indication in Q4 2016.

We have completed target enrollment in the ARIEL3 pivotal maintenance study, with data expected to be available in approximately 12 months. Pending positive data, Clovis intends to follow up with supplemental NDAs for maintenance indications in tumor BRCA mutant patients and BRCA-like patients.

Clovis recently entered into a clinical trial collaboration with Genentech, a member of the Roche Group, to evaluate a novel combination therapy of Genentech's investigational cancer immunotherapy atezolizumab (MPDL3280A; anti-PDL1) and rucaparib for the treatment of gynecological cancers, with a focus on ovarian cancer. The Phase 1b trial is planned to begin enrolling patients during the second half of 2016.

Also during the second half of 2016, the Company intends to initiate a study of rucaparib in metastatic castrate-resistant BRCA mutant (inclusive of germline and somatic) prostate cancer patients, as well as the ARIEL4 confirmatory study in advanced ovarian cancer.

Rociletinib

In a recent meeting with the FDA, Clovis was notified that it could anticipate receiving a Complete Response Letter (CRL) for the rociletinib NDA on or before the PDUFA date of June 28, 2016. The FDA issues a CRL to indicate that their review of an application is complete and that the application is not ready for approval. In anticipation of receiving the CRL, Clovis has terminated enrollment in all ongoing sponsored clinical studies of rociletinib. Clovis will continue to provide drug to patients whose clinicians recommend continuing rociletinib therapy. In addition, Clovis has withdrawn its MAA for rociletinib previously filed with European regulatory authorities. Related to terminating enrollment in all ongoing sponsored clinical studies of rociletinib, Clovis is reducing its staff, eliminating contractor positions and delaying or eliminating planned new positions. This will result in the reduction of our staff and contractor positions by 35 percent by the end of 2016, compared to year-end 2015.

However, we intend to maintain the U.S. sales force in preparation for the potential U.S. launch of rucaparib. Clovis has determined there would be effectively no cost savings in eliminating the U.S. sales force and replacing it with a contract organization to support the potential U.S. launch of rucaparib in Q4 2016 or Q1 2017. In addition, a decision to use a contract sales organization could potentially delay the timing of the U.S. launch.

Lucitanib

Enrollment was completed during the first quarter in the ongoing Phase 2 study exploring lucitanib in patients with treatment-refractory breast cancer. In parallel with Clovis' sponsored study, a Servier-sponsored Phase 2 study of lucitanib in patients with advanced breast cancer is underway to identify the population of patients most likely to benefit from lucitanib therapy. The Company expects to make a decision regarding the future development of lucitanib by the end of 2016.

Conference Call Details

Clovis will hold a conference call to discuss first quarter 2016 results this afternoon, May 5, at 4:30pm ET. The conference call will be simultaneously webcast on the Company's web site at www.clovisoncology.com, and archived for future review. Dial-in numbers for the conference call are as follows: US participants 866.489.9022, International participants 678.509.7575, conference ID: **2018033**.

About Rucaparib

Rucaparib is an oral, potent small molecule inhibitor of PARP1-3 being developed for the treatment of ovarian cancer, specifically in patients with tumors with BRCA mutations and other DNA repair deficiencies beyond BRCA, including those with high genomic loss of heterozygosity (LOH) commonly referred to as "BRCA-like." Clovis is also exploring rucaparib in other solid tumor types with significant BRCA and BRCA-like populations, including prostate, breast and gastroesophageal cancers. Rucaparib was granted Breakthrough Therapy designation by the U.S. FDA in April 2015. Clovis holds worldwide rights for rucaparib.

About Rociletinib

Rociletinib is an oral, mutant-selective inhibitor of epidermal growth factor receptor (EGFR). Rociletinib targets the activating mutations of EGFR (L858R and Del19), while also inhibiting the dominant acquired resistance mutation, T790M. Clovis holds worldwide rights for rociletinib.

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 (PDGFRα-β) and fibroblast growth factor receptors 1 through 3 (FGFR1-3). Clovis, which holds exclusive U.S. and Japanese rights, is collaborating with its development partner Les Laboratoires Servier (Servier) on the global clinical development of lucitanib outside of China, initially targeting advanced breast cancer.

About Clovis Oncology

Clovis Oncology, Inc. is a biopharmaceutical company 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 diagnostic tools that direct a compound in development to the population that is most likely to benefit from its use. Clovis Oncology is headquartered in Boulder, Colorado.

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. Such forward-looking statements involve substantial risks and uncertainties that could cause our clinical development programs, 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 uncertainties inherent in our clinical development programs for our drug candidates, the corresponding development pathways of our companion diagnostics, actions by the FDA, the

EMA or other regulatory authorities regarding whether to approve drug applications that may be filed, as well as their decisions regarding drug labeling, and other matters that could affect the availability or commercial potential of our drug candidates or companion diagnostics, including competitive developments. 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
(in thousands, except per share amounts)

	Three Months Ended March 31,	
	2016	**2015**
Revenues:		
License and milestone revenue	$ -	$ -
Operating expenses:		
Research and development	74,608	56,750
General and administrative	9,827	6,751
Accretion of contingent purchase consideration	516	724
Total expenses	84,951	64,225
Operating loss	(84,951)	(64,225)
Other income (expense):		
Interest expense	(2,104)	(2,075)
Foreign currency gains (losses)	(551)	3,247
Other income (expense)	25	11
Other income (expense), net	(2,630)	1,183
Loss before income taxes	(87,581)	(63,042)
Income tax expense	4,181	(102)
Net loss	$ (83,400)	$ (63,144)
Basic and diluted net loss per common share	$ (2.17)	$ (1.86)
Basic and diluted weighted-average common shares outstanding	38,360	34,011

CONSOLIDATED BALANCE SHEET DATA
(in thousands)

	March 31, 2016	December 31, 2015
Cash and cash equivalents	$ 220,373	$ 278,756

Available-for-sale securities	225,117	249,832
Working capital	390,030	464,125
Total assets	644,574	713,386
Convertible senior notes	280,192	279,885
Common stock and additional paid-in capital	1,141,686	1,130,016
Total stockholders' equity	232,663	300,650

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