Clovis Oncology Announces Regulatory Update for Rociletinib NDA Filing

November 16, 2015 8:00 AM ET

- *Mid-Cycle Communication Meeting with FDA completed*
- *Additional clinical information for 500mg and 625mg BID dose groups to be provided by the Company today*

BOULDER, Colo.--(BUSINESS WIRE)--Nov. 16, 2015-- Clovis Oncology, Inc. (NASDAQ: CLVS) today announced that during its regularly scheduled Mid-Cycle Communication Meeting held last week with the U.S. Food and Drug Administration (FDA), the agency requested additional clinical data for use in the efficacy analysis for both the 500mg and 625mg BID dose patient groups for rociletinib. The Company will provide this information in a Major Amendment to the FDA by close of business today.

“We remain confident in rociletinib and its potential to treat patients with mutant EGFR T790M-positive lung cancer, said Patrick J. Mahaffy, President and CEO of Clovis Oncology. “We will continue to work diligently with the FDA on our NDA submission.”

In the Mid-Cycle Communication meeting, the FDA emphasized that its efficacy analysis would focus solely on confirmed responses. The New Drug Application (NDA) submitted by Clovis to the FDA contained immature data sets based on both unconfirmed response rates and confirmed response rates. These data sets were updated in the 90 day efficacy update the Company submitted at the end of October.

As the rociletinib clinical trials were rapidly enrolling, Clovis presented interim data publicly and at medical meetings and these data therefore included a data set based primarily on unconfirmed responses. This was also true of the Company’s Breakthrough Therapy designation submission. In the Company’s NDA submission, both immature confirmed and unconfirmed response analyses were submitted. As the efficacy data have matured, the number of patients with an unconfirmed response who converted to a confirmed response was lower than expected.

In the intent to treat analysis of the 79 patients in the 500mg dose group, the current confirmed response rate is 28 percent, and 34 percent in the 170 patients in the 625mg dose group, with an encouraging duration of response in both doses. The most frequent reasons that patients’ responses were not confirmed in a subsequent scan were due to progression, often due to brain metastasis, and due to subsequent scans not demonstrating tumor shrinkage greater than 30 percent.

The Company anticipates that the review of this additional information will result in a delay of a potential approval. This additional review could lead to an extension of the Company’s March 30, 2016 Prescription Drug User Fee Act (PDUFA) date.

Conference Call Details

Clovis will hold a conference call to discuss this regulatory update later this morning, November 16, at 8:30am 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 800 884.5695, International participants 617 786.2960, conference ID: 71037009

About Rociletinib

Rociletinib is the company’s novel, oral, targeted covalent (irreversible) mutant-selective inhibitor of EGFR in development for the treatment of NSCLC in patients with initial activating EGFR mutations, as well as the dominant resistance mutation T790M. Data from both the pivotal, single-arm TIGER-X and TIGER-2 clinical trials served as the basis for the U.S. and EU regulatory submissions for the treatment of advanced mutant EGFR T790M-positive lung cancer. Rociletinib was given Breakthrough Therapy designation by the FDA in May 2014.

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.

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