Clovis Oncology Announces Rociletinib New Drug Application Scheduled for Presentation at Upcoming FDA Oncologic Drugs Advisory Committee Meeting

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BOULDER, Colo.--(BUSINESS WIRE)--Feb. 12, 2016-- Clovis Oncology, Inc. (NASDAQ: CLVS) announced today that the U.S. Food and Drug Administration (FDA) has scheduled the New Drug Application (NDA) for rociletinib for discussion by the Oncologic Drugs Advisory Committee (ODAC) on April 12, 2016. Rociletinib is an investigational therapy for the treatment of patients with mutant epidermal growth factor receptor (EGFR) non-small cell lung cancer (NSCLC) who have been previously treated with an EGFR-targeted therapy and have the EGFR T790M mutation.

The ODAC reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of cancer and makes recommendations to the FDA.

“We are actively preparing for this advisory committee meeting and look forward to the discussion about rociletinib,” said Patrick J. Mahaffy, President and CEO of Clovis Oncology. “New treatments are needed for this hard-to-treat patient population, and we believe that rociletinib represents an important new option for patients with mutant EGFR T790M-positive lung cancer.”

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 granted 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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