Clovis Oncology Provides Update on FDA Oncologic Drugs Advisory Committee Meeting to Review Rociletinib for Treatment of Advanced T790M-Positive Mutant Epidermal Growth Factor Receptor Non-Small Cell Lung Cancer

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BOULDER, Colo.--(BUSINESS WIRE)--Apr. 12, 2016-- Clovis Oncology, Inc. (NASDAQ: CLVS) announced today that the U.S. Food and Drug Administration (FDA) Oncologic Drugs Advisory Committee (ODAC) met to discuss approval of the New Drug Application (NDA) for rociletinib, 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 T790M mutation.

The Committee recommended that the FDA wait to see results from TIGER-3, Clovis' ongoing Phase 3, randomized, controlled trial of rociletinib, before making a decision on approval of the treatment. Patient enrollment for the trial is expected to complete in late 2018.

"We are disappointed with today's outcome, as we believe in the strength of the data we presented for rociletinib," said Patrick J. Mahaffy, President and CEO of Clovis Oncology. "We will work with the FDA to evaluate the best path forward as it continues to review our application."

The FDA set a target action date of June 28, 2016 under the Prescription Drug User Fee Act (PDUFA). The TIGER-3 trial, Clovis' confirmatory randomized, controlled Phase 3 study for rociletinib, is ongoing, with patient enrollment expected to complete in late 2018.

About T790M-Positive Mutant EGFR NSCLC

Lung cancer is the second most common cancer in the United States, with more than 200,000 new cases each year, and is the leading cause of cancer-related death. NSCLC accounts for almost 85 percent of lung cancers, and the five-year survival rate in locally advanced and metastatic patients is 27 percent and four percent, respectively.

Approximately 15 percent of patients with NSCLC have the EGFR mutation. While the majority of these patients will respond to treatment with first- or second-generation EGFR-targeted tyrosine kinase inhibitors (TKIs), almost all patients will eventually develop acquired resistance to these therapies, predominantly due to the primary resistance mutation, T790M.

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 United States, 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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