Clovis Oncology Initiates Rolling NDA Submission to the FDA for Rociletinib in the Treatment of Advanced EGFR-Mutant Non-small Cell Lung Cancer

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NDA submission is expected to complete by late July

BOULDER, Colo.--(BUSINESS WIRE)--Jul. 1, 2015--

Clovis Oncology, Inc. (NASDAQ: CLVS) announced today that it has commenced the submission of a New Drug Application (NDA) regulatory filing to the U.S. Food and Drug Administration (FDA) for rociletinib 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 as detected by an FDA approved test. 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.

Rociletinib was granted Breakthrough Therapy designation by the FDA in May 2014. Clovis agreed with FDA that the submission would be a rolling NDA and has filed the first component for potential accelerated approval of rociletinib 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 late July 2015.

“The initiation of this rolling submission represents a very important first step toward our biggest milestone of 2015 – the submission of our first NDA for rociletinib as treatment for patients with T790M-positive EGFR-mutant non-small cell lung cancer,” said Patrick J. Mahaffy, President and CEO of Clovis Oncology. “We look forward to completing the NDA by the end of July, and are actively preparing for our first commercial launch.”

In addition, the Company intends to complete the Marketing Authorization Application (MAA) for rociletinib to the European Medicines Agency at the end of July.

About Rociletinib

Rociletinib is an oral, potent, mutant-selective inhibitor of epidermal growth factor receptor (EGFR) under investigation for the treatment of EGFR-mutated non-small cell lung cancer (NSCLC). Rociletinib targets the activating mutations of EGFR (L858R and Del19), while also inhibiting the dominant acquired resistance mutation, T790M, which develops in approximately 60 percent of patients treated with first- and second-generation EGFR inhibitors, while sparing wild-type, or “normal” EGFR at anticipated therapeutic doses. Accordingly, it has the potential to treat NSCLC patients with EGFR mutations both as a first-line or second-line treatment with a potentially reduced toxicity profile. Rociletinib was granted Breakthrough Therapy designation by the U.S. FDA in May 2014.

About Rociletinib Clinical Development

Clovis is currently enrolling several studies in EGFR-mutant NSCLC:

- TIGER-X is a Phase 1/2 study designed to evaluate the safety and efficacy of three different doses of rociletinib in a very advanced patient population.
- TIGER-1 is a randomized Phase 2/3 registration study versus erlotinib in newly-diagnosed patients.
- TIGER-2 is a global registration study underway in both T790M-positive and T790M-negative patients directly after progression on their first and only TKI therapy.
- TIGER-3 is a randomized, comparative study versus chemotherapy in both T790M-positive and T790M-negative patients with acquired TKI resistance.
- A Phase 1 study of rociletinib in Japan has completed enrollment and a Phase 2 study in Japanese patients, agreed
upon with Japanese regulatory authorities, is expected to initiate in the second half of 2015.

- Multiple combination studies are planned to initiate in the second half of 2015, including inhibitors of PD-L1, PD-1 and MEK.
- For more information, please visit www.tigertrials.com.

About Lung Cancer and EGFR Mutations

Lung cancer is the most common cancer worldwide with 1.35 million new cases annually, with NSCLC accounting for almost 85 percent of all lung cancers. NSCLC progresses rapidly with a five-year survival rate in advanced NSCLC patients of less than five percent. EGFR activating mutations occur in approximately 10 to 15 percent of NSCLC cases in Caucasian patients and approximately 30 to 35 percent in East Asian patients. These patients often experience significant tumor response to erlotinib, afatinib and gefitinib, which are first- and second-generation EGFR inhibitors. However, most patients ultimately progress on these therapies, with approximately 60 percent of patients developing acquired resistance from a second, “gatekeeper” mutation, T790M. Currently, no targeted therapies are approved for treatment of this mutation.

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.


Source: Clovis Oncology

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