Clovis Oncology Announces Clinical Data to be Presented at ASCO Annual Meeting 2013

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BOULDER, Colo.--(BUSINESS WIRE)--May. 16, 2013-- Clovis Oncology (NASDAQ:CLVS) announced that three abstracts (ASCO Abstracts #2524, #2585, #2586) highlighting results from three Phase I studies of the company’s two lead compounds will be presented at the American Society of Clinical Oncology (ASCO) Annual Meeting 2013 in Chicago.

Data contained in the published abstracts was current as of the submission deadline of February 5th, 2013. Data to be presented in the poster sessions will include data from the trials as of early May.

Clovis is developing CO-1686, a novel, oral, targeted covalent (irreversible) inhibitor of the epidermal growth factor receptor (EGFR), for the treatment of non-small cell lung cancer (NSCLC), in patients with initial activating EGFR mutations as well as the T790M primary resistance mutation. Rucaparib, an oral, potent, small molecule poly (ADP-ribose) polymerase (PARP) inhibitor, is being developed for ovarian cancer. Both compounds are in the Phase I dose-escalation portion of Phase I/II clinical trials.

The abstracts accepted for poster presentation, all as part of the Developmental Therapeutics – Clinical Pharmacology & Experimental Therapeutics Session, are as follows:

(Abstract #2524) First in-human evaluation of CO-1686, an irreversible, selective, and potent tyrosine kinase inhibitor of EGFR T790M.

- Dr. Lecia V. Sequist, Massachusetts General Hospital, Boston
- Tuesday, June 4, 8:00 a.m. - 12:00 p.m. CDT
- Location: E450a

The poster will be discussed at the associated discussion session:

- Dr. David Carbone, Ohio State’s Comprehensive Cancer Center – James Cancer Hospital and Solove Research Institute.
- Tuesday, June 4, 11:30 a.m. - 12:30 p.m. CDT (Dr. Carbone is scheduled to speak from 11:54 a.m. – 12:06 p.m.)
- Location: E354b, Poster #12

(Abstract #2585) A phase I dose escalation and PK study of continuous oral rucaparib in patients with advanced solid tumors.

- Dr. Rebecca Kristeleit, University College of London Cancer Institute, London
- Monday, June 3, 8:00 a.m. – 11:45 a.m.
- Location: S Hall A2, Poster Board: 7E

(Abstract #2586) A phase I study of oral rucaparib in combination with carboplatin.

- Dr. L. Rhoda Molife, The Royal Marsden and Institute of Cancer Research, Surrey, UK
- Monday, June 3, 8:00 a.m. – 11:45 a.m.
- Location: S Hall A2, Poster Board: 7F

About CO-1686

CO-1686 is a novel, oral, targeted covalent (irreversible) inhibitor of the cancer-causing mutant forms of epidermal growth factor receptor (EGFR) currently being studied for the treatment of non-small cell lung cancer (NSCLC). CO-1686 was designed to selectively target both the initial activating EGFR mutations as well as the T790M resistance mutation, 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 reduced toxicity profile compared to current EGFR inhibitor therapies. The Phase I/II study is currently in the dose escalation phase, being conducted at six sites in the U.S. and Europe. Following the establishment of an appropriate dose, the Company intends to study CO-1686 in a Phase II expansion cohort of NSCLC patients with activating EGFR mutations who have failed initial EGFR-directed therapy and have developed the T790M mutation, as well as a second expansion cohort of first-line mutant EGFR NSCLC patients.
About Rucaparib

Rucaparib is an oral, potent inhibitor of PARP1 and PARP2 in development for the treatment of ovarian cancer. Rucaparib is currently in two Company-sponsored Phase I clinical studies; one to determine the maximum tolerated dose (MTD) of oral rucaparib administered on a daily basis as monotherapy; and a second trial to determine the MTD of oral rucaparib that can be combined with intravenous platinum chemotherapy for the treatment of solid tumors. Once the optimal dose and schedule have been established in the monotherapy study, the Company will initiate a Phase II expansion cohort to assess efficacy in selected ovarian cancer patients. The Company expects to initiate a biomarker study in platinum-sensitive ovarian cancer patients in the third quarter of 2013, as well as the pivotal Phase III study in platinum-sensitive ovarian cancer patients in late 2013.

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, and has additional offices in San Francisco, California and Cambridge, UK.

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 the initiation of future clinical trials, availability of data from ongoing clinical trials, expectations for regulatory approvals, and other matters that could affect the availability or commercial potential of our drug candidates. Clovis Oncology undertakes no obligation to update or revise any forward-looking statements. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to the business of the company in general, see Clovis Oncology’s Annual Report on Form 10-K for the year ended December 31, 2012 and its other reports filed with the Securities and Exchange Commission.

Source: Clovis Oncology

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