Clovis Oncology Announces Data Presentations at 2015 ASCO Annual Meeting

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- Rociletinib oral presentation on Sunday, May 31 to update TIGER-X clinical data in heavily pretreated, advanced EGFR-mutant lung cancer patients, including in plasma-genotyped T790M-positive patients
- Rucaparib oral presentation on Monday, June 1 to include outcomes data from full ARIEL2 part one population of ~200 women with advanced ovarian cancer
- Rociletinib rolling NDA submission for EGFR-mutant lung cancer expected to commence next month; complete by July/August
- NDA filing for rucaparib planned for treatment of advanced ovarian cancer in 2016
- Rociletinib and rucaparib granted Breakthrough Therapy designation in last 12 months

BOULDER, Colo.--(BUSINESS WIRE)--May 13, 2015-- Clovis Oncology (NASDAQ:CLVS) today announced that two oral presentations and six poster sessions highlighting updated results and trial designs from clinical studies of the company’s three compounds in advanced clinical development are being presented at the 2015 American Society of Clinical Oncology (ASCO) Annual Meeting, which will take place May 29-June 2, 2015 in Chicago.

“Our data at ASCO this year include an update from our TIGER-X study of rociletinib in EGFR-mutated non-small cell lung cancer, which together with data from TIGER-2, will serve as the basis of our intended rolling NDA submission to commence next month, as well as the first look at the full population of ovarian cancer patients in part one of the ARIEL2 study of rucaparib, which will contribute to our planned 2016 NDA submission,” said Patrick J. Mahaffy, CEO and President of Clovis Oncology. “We are pleased that these data were selected for oral presentations at ASCO this year, and that the FDA has recognized the compelling results observed for both of these compounds by granting Breakthrough Therapy designation for each in the past twelve months.”

Rociletinib, the Company’s 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) is the subject of an oral presentation and two posters:

Abstract 8001 – Efficacy of rociletinib (CO-1686) in plasma-genotyped T790M-positive non-small cell lung cancer (NSCLC) patients (pts)

- Lecia V. Sequist, MD, MPH, Massachusetts General Hospital
- Lung Cancer – Non-Small Cell Metastatic
- Sunday, May 31, 8:00 a.m. – 11:00 a.m. (Rociletinib oral presentation: 8:12 - 8:24 a.m.)
- Location: N Hall B1

Abstract TPS8108 – TIGER-1: A randomized, open-label, phase 2/3 study of rociletinib (CO-1686) or erlotinib as first-line treatment for EGFR-mutant non-small cell lung cancer (NSCLC)

- D. Ross Camidge, MD, PhD, University of Colorado Cancer Center
- Monday, June 1, 8:00 a.m. – 11:30 a.m.
- Location: S Hall A; Poster Board #430a

Abstract TPS8109 – TIGER-3: A phase 3, open-label, randomized study of rociletinib vs cytotoxic chemotherapy in patients (pts) with mutant EGFR non-small cell lung cancer (NSCLC) progressing on prior EGFR TKI therapy and doublet chemotherapy

- James C. Yang, MD, PhD, Department of Oncology, National Taiwan University Hospital; Graduate Institute of Oncology & Cancer Research Center, National Taiwan University
- Monday, June 1, 8:00 a.m. – 11:30 a.m.
Rucaparib, the Company’s oral, potent, small molecule inhibitor of PARP1 and PARP2 being developed for the treatment of ovarian cancer, specifically in patients with tumors with BRCA mutations and other DNA repair deficiencies beyond BRCA, commonly referred to as “BRCA-like”, is the subject of an oral presentation and four posters:

Abstract 5508 – Results of ARIEL2: a Phase 2 trial to prospectively identify ovarian cancer patients likely to respond to rucaparib using tumor genetic analysis

- Iain A McNeish, PhD FRCP, Institute of Cancer Sciences, University of Glasgow
- Gynecologic Cancer
- Monday, June 1, 8:00 a.m. – 11:00 a.m. (Rucaparib oral presentation: 10:24 – 10:36 a.m)
- Location: E354b

Abstract 5513 – A phase II open-label, multicenter study of single-agent rucaparib in the treatment of patients with relapsed ovarian cancer and a deleterious BRCA mutation

- Ronnie Shapira-Frommer, MD, Sheba Medical Center
- Saturday, May 30, 1:15 p.m. - 4:45 p.m.
- Location: S Hall A; Poster Board #71
- Poster discussion session: 4:45 p.m. – 6:00 p.m. in E354b

Abstract 5539 – Tumor biopsies in high grade ovarian cancer: Clinical utility and challenges for biomarker-directed therapy

- Michelle K. Wilson, MBChB, FRACP, Princess Margaret Cancer Centre
- Saturday, May 30, 1:15 p.m. - 4:45 p.m.
- Location: S Hall A; Poster Board #97

Abstract 1082 – Cisplatin with or without rucaparib after preoperative chemotherapy in patients with triple negative breast cancer: Final efficacy results of Hoosier Oncology Group BRE09-146

- Kathy Miller, MD, Indiana University Melvin and Bren Simon Cancer Center
- Saturday, May 30, 8:00 a.m. – 11:30 a.m.
- Location: S Hall A; Poster Board #196

Lucitanib, the Company’s oral, potent inhibitor of the tyrosine kinase activity of fibroblast growth factor receptors 1 through 3 (FGFR1-3), vascular endothelial growth factor receptors 1 through 3 (VEGFR1-3), and platelet-derived growth factor receptors alpha and beta (PDGFRα-β) in development for breast and lung cancers, is the subject of one poster:

Abstract TPS628 – A phase 2, randomized, open-label study of lucitanib in patients with FGF aberrant metastatic breast cancer

- Maysa M. Abu-Khalaf, MD, Yale Cancer Center, Yale School of Medicine
- Saturday, May 30 8:00 a.m. - 11:30 a.m.
- Location: S Hall A; Poster Board #115b

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 Rucaparib

Rucaparib is an oral, potent small molecule inhibitor of PARP1 and PARP2 being developed for the treatment of ovarian cancer, specifically in patients with tumors with BRCA mutations and other DNA repair deficiencies beyond BRCA, commonly referred to as “BRCA-like.” Rucaparib was granted Breakthrough Therapy designation by the U.S. FDA in April 2015.

About Lucitanib

Lucitanib is an oral, potent inhibitor of the tyrosine kinase activity of fibroblast growth factor receptors 1 through 3 (FGFR1-3), vascular endothelial growth factor receptors 1 through 3 (VEGFR1-3), and platelet-derived growth factor receptors alpha and beta (PDGFRα-β). Clovis, which holds exclusive U.S. and Japanese rights, is collaborating with its development partner Les Laboratoires Servier (Servier) on the global clinical development of lucitanib outside of China, initially targeting solid tumors with FGFR pathway activation, including breast and lung cancers.

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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