Clovis Oncology Announces Clinical Data to Be Presented at 2014 ASCO Annual Meeting

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Abstracts provide updates on the Company’s three investigational therapies in development:

- CO-1686, an oral, novel mutant EGFR inhibitor for non-small cell lung cancer (NSCLC)
- Rucaparib, an oral PARP inhibitor for ovarian cancer, and
- Lucitanib, an oral tyrosine-kinase inhibitor for breast cancer and squamous NSCLC

BOULDER, Colo.--(BUSINESS WIRE)--May 14, 2014-- Clovis Oncology (NASDAQ:CLVS) announced that five abstracts highlighting clinical progress and results from Phase 1 and 2 studies of the company’s three compounds will be presented at the 2014 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago.

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 and is also being explored in BRCA-mutated pancreatic cancer. Lucitanib, an oral tyrosine kinase inhibitor targeting multiple growth factors and receptors, is being evaluated in FGF-aberrant breast cancer and squamous NSCLC.

Data from trials of CO-1686 and lucitanib will be presented in the following oral presentation sessions:

(Abstract #8010) First-in-human evaluation of CO-1686, an irreversible, highly selective tyrosine kinase inhibitor of mutations of EGFR (activating and T790m)

- Lecia Sequist, MD, MPH, Massachusetts General Hospital
- Clinical Science Symposium - Targeting EGFR: The Next 10 Years
- Saturday, May 31, 8:00 a.m. - 9:30 a.m. (CO-1686 presentation: 8:12 a.m. - 8:24 a.m.)
- Location: E Hall D1

(Abstract #2500) A Phase I/IIa study evaluating the safety, efficacy, pharmacokinetics, and pharmacodynamics of lucitanib in advanced solid tumors

- Jean-Charles Soria, MD, Gustave Roussy Institute
- Developmental Therapeutics – Clinical Pharmacology and Experimental Therapeutics
- Saturday, May 31, 1:15 p.m. - 4:15 p.m. (Lucitanib presentation: 1:15 p.m. – 1:27 p.m.)
- Location: E Hall D2

The following three rucaparib abstracts will be discussed during poster presentations:

(Abstract #TPS5619/Poster #397A) ARIEL 2/3: An integrated clinical trial program to assess activity of rucaparib in ovarian cancer and to identify tumor molecular characteristics predictive of response.

- Elizabeth M. Swisher, MD, University of Washington School of Medicine, Seattle, WA
- Saturday, May 31 8:00 a.m. - 11:45 a.m.
- Location: S Hall A2

(Abstract #TPS4161/Poster #239B) A phase 2, open-label study of rucaparib in patients with pancreatic cancer and a known deleterious BRCA mutation

- Susan M. Domchek, MD, The University of Pennsylvania, Philadelphia, PA
- Saturday, May 31, 8:00 a.m. - 11:45 a.m.
- Location: S Hall A2
(Abstract #2573/Poster #36) Phase 1/2 study of oral rucaparib: Final phase 1 results

- Rebecca Sophie Kristeleit, MD, PhD, University College of London Cancer Institute
- Sunday, June 1, 8:00 a.m. - 11:45 a.m.
- Location: S Hall A2

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 potentially reduced toxicity profile.

About Rucaparib

Rucaparib is an oral, potent small molecule inhibitor of PARP1 and PARP2 being developed for the treatment of platinum-sensitive, relapsed ovarian cancer in patients with BRCA mutations (genes that are linked to hereditary breast and ovarian cancers) and other DNA repair deficiencies. Rucaparib is also being explored in patients with BRCA-mutant pancreatic cancer.

About Lucitanib

Lucitanib is an oral, potent inhibitor of the tyrosine kinase activity of fibroblast growth factor receptors 1 and 2 (FGFR1-2), 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, initially targeting solid tumors with FGFR pathway activation, including breast and squamous NSCLC.

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, Inc.

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