BOULDER, Colo.--(BUSINESS WIRE)--Sep. 10, 2014-- Clovis Oncology (NASDAQ:CLVS) today announced that its Phase 2 study of lucitanib in patients with FGF-aberrant, advanced breast cancer has commenced and the first patient dosed at a U.S. study site. Lucitanib is the Company’s 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 (PDGFR α-β).

“Early lucitanib data are encouraging, and suggest that determination of genetic alterations in the FGF pathway may be important to identify the patients most likely to benefit from lucitanib treatment,” said Professor Carlos L. Arteaga, MD, Associate Director for Clinical Research, Director of the Center for Cancer Targeted Therapies, and Director of the Breast Cancer Program at the Vanderbilt-Ingram Cancer Center of Vanderbilt University. “This study will further explore two doses of lucitanib in patients with FGF-aberrant breast cancer, a population which possesses these genetic alterations, and for whom new treatment options are needed.”

“We are pleased to move forward with our study of lucitanib in patients with FGF-aberrant breast cancer, which complements the Servier programs already underway,” said Patrick J. Mahaffy, President and CEO of Clovis Oncology. “The Phase 1/2a data presented to date are compelling and we look forward to confirming the optimal dose and schedule of lucitanib in this study.”

The Phase 2, open-label, randomized, multi-center study will enroll approximately 160 patients with FGFRI or 11q-amplified, advanced breast cancer. The study will further evaluate the lucitanib dosing strategy, by comparing the progression-free survival of patients receiving 10mg or 15mg daily. The study will also assess overall response rate, duration of response, safety, tolerability, and pharmacokinetics of lucitanib.

Lucitanib is unique among tyrosine kinase inhibitors being developed for cancer therapy in effectively targeting fibroblast growth factor receptors (FGFR)1-2, vascular endothelial growth factor receptors (VEGFR)1-3, and platelet-derived growth factor (PDGF) receptors alpha and beta with minimal off-target activity. This selectivity profile allows lucitanib to provide a potential benefit to cancer patients by targeting multiple pathways of tumor development. Specifically, by targeting the FGFR pathway, lucitanib can have a direct antitumor effect in FGF/FGFR-driven tumors such as breast or lung cancers harboring amplification of the FGFR1 gene. In addition, by targeting the FGFR, VEGFR and PDGFR receptors, lucitanib also can inhibit the development of blood vessels that are required by the tumor to grow and spread.

This study is part of a global development program for lucitanib in breast cancer, which includes the Servier-sponsored FINESSE study of lucitanib monotherapy being conducted in Europe, Canada and Australia as well as the Servier-sponsored INES study evaluating lucitanib in combination with fulvestrant after failure of endocrine therapy. In addition, a Clovis-sponsored Phase 2 study evaluating lucitanib in patients with FGFRI-amplified, squamous non-small cell lung cancer is scheduled to begin shortly.

About FGF-aberrant Breast Cancer

Breast cancer includes three main molecular classes: estrogen receptor positive (ER+)/ human epidermal growth factor receptor 2 (HER2)-negative breast cancers, HER2-overexpressing breast cancer, and triple negative breast cancers. While these three subtypes of metastatic breast cancer are treated with different drugs and have distinct prognoses, these patients eventually develop resistance or intolerance to approved drugs. Metastatic breast cancer remains an incurable disease, with approximately 41,000 disease-associated deaths in the United States annually. In many cases, resistance to approved anti-cancer drugs is mediated by activation of the FGF pathway through amplification of FGF-related genes. Specifically, the gene coding for fibroblast growth factor receptor 1 (FGFRI) is amplified in roughly 10 percent of invasive
breast cancers and approximately 15 percent demonstrate amplification of the chromosome region 11q (amplicon) that contains genes that code for FGF3, FGF4, and FGF19 proteins. These amplification events have been associated with increased signaling in the FGF/FGFR pathway, neo-angiogenesis, and resistance to targeted and endocrine therapies.

**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 (PDGFR α-β). Clovis owns exclusive development and commercial rights to lucitanib on a global basis, excluding China. Lucitanib rights to markets outside of the U.S. and Japan have been sublicensed to Servier. Clovis is collaborating with Servier on the global clinical development of lucitanib.

**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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