Pfizer Logo

Clovis Oncology, Inc. Receives License for Worldwide Development and Commercialization Rights to Pfizer's Oral and IV PARP Inhibitor PF-01367338

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• PF-01367338 is currently in Phase 1/2 development in combination with chemotherapy in patients with solid tumors
• Phase 2 data from IV formulation demonstrate encouraging activity and safety profile
• Clovis to assume responsibility for all development and commercial activities worldwide
• Pfizer to invest in Clovis Oncology

Clovis Oncology, Inc. announced today an agreement with Pfizer Inc. (NYSE: PFE) for the development and commercialization of Pfizer's oral and IV Poly (ADP-ribose) polymerase (PARP) inhibitor, PF-01367338, currently in Phase 1/2 development for solid tumors. PF-01367338 is a novel, orally active, small molecule inhibitor of PARP and will be developed by Clovis as both a monotherapy and in combination with chemotherapeutic agents for the potential treatment of selected cancer patients.

Under the terms of the agreement, Clovis Oncology will take over responsibility for global product development and commercialization. Pfizer will receive an upfront license fee from Clovis, payable in equity in Clovis Oncology, and will be eligible to receive further payments totaling up to $255 million upon Clovis Oncology's successful attainment of development, regulatory and sales milestones. Pfizer will also receive royalties on any product sales. In addition, Pfizer Venture Investments, the venture capital arm of Pfizer, will make a separate equity investment in Clovis Oncology.

"This drug is a very potent PARP inhibitor. It has already demonstrated very encouraging activity as an IV formulation and now we know that the oral formulation is also active. This potentially opens up many exciting opportunities for long-term treatment for cancer patients," said Professor Hilary Calvert, Director of Cancer Drug Discovery and Development at University College London, UK, and a pioneer in the field of human cancer therapy with PARP inhibitors. "We know that PARP inhibitors are active in germline BRCA-mutant (gBRCA) tumors, and that this activity extends beyond this group of tumors into broader patient populations in ovarian cancer and may do so in other cancers as well. I am delighted to work with Clovis to quickly bring this promising new therapy forward," he added.

PF-01367338 is currently in a Phase 1 clinical trial examining the maximum tolerated dose of oral PF-01367338 that can be combined with intravenous platinum chemotherapy in the treatment of solid tumors. This program is supplemented by two ongoing trials, currently using the IV formulation: a Phase 1/2 study in gBRCA breast and ovarian cancer and a Phase 2 study in the adjuvant treatment of triple negative breast cancer. Clovis Oncology intends to replace the IV formulation with the oral formulation in these studies.

“We are pleased to add PF-01367338 to our pipeline and appreciate Pfizer’s belief in our organization and in the development plans we have for the drug. It has long been evident that inhibiting PARP may provide significant benefit to patients with many tumor types. We are particularly attracted to this compound because its profile suggests not only that it could be used in combination with chemotherapy but could potentially be used as monotherapy for the long term management of disease,” said Patrick J. Mahaffy, President and CEO of Clovis Oncology. “It is also evident that patient selection is very important in the development of a PARP inhibitor, and as we have for each of our other drugs, we will seek to partner with a diagnostic company to aid in the selection of the right patients for this drug. Clovis is building an organization dedicated to the development of drugs with companion diagnostics, and we are gaining experience in managing the complicated processes required to efficiently enable this strategy. ”

“Clovis Oncology is the ideal choice to continue the development and commercialization of PF-01367338,” said Garry Nicholson, President and General Manager, Pfizer Oncology. “With the number of molecules in Pfizer’s oncology pipeline, we have the opportunity to work together with innovative companies and realize greater potential from our oncology portfolio. This agreement is a perfect example of our effort to set priorities and to collaborate in the interest of cancer patients worldwide.”

About PARP

Poly (ADP-ribose) polymerase (PARP) is a nuclear enzyme involved in DNA repair and programmed cell death. In noncancerous cells, DNA repair is beneficial and promotes normal growth and proliferation of cells. DNA repair enzymes such as PARP, whose activity and expression are up regulated in tumor cells, are believed to contribute to resistance and dampen the effects of chemotherapy. Therefore, inhibition of PARP can prevent the repair of single strand DNA breaks, which in turn causes double strand DNA breaks and ultimately leads to cancer cell death. Additionally, PARP inhibitors may be particularly effective in treating tumors with impaired DNA repair function, including those with BRCA 1 and BRCA 2 mutations. The use of PARP inhibitors in the clinic has focused primarily on inducing cancer cell death in patients with hereditary mutations in BRCA 1/2 and in patients with tumors characterized by defective DNA repair, including breast, ovarian, prostate and other tumor types.

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 intends to target development programs at specific subsets of cancer populations, and will simultaneously develop diagnostic tools that direct a compound in development to the population that is most likely to benefit from its use. The Company is currently developing CO-101, which is in a pivotal study for the treatment of pancreatic cancer and CO-1686, an epidermal growth factor receptor (EGFR) mutant-selective inhibitor (EMSI) which is currently in pre-clinical development for non-small cell lung cancer (NSCLC) patients who express the T790M mutation. The Company is headquartered in Boulder, Colorado, and has additional offices in San Francisco and Cambridge, England.

For more information about Clovis Oncology, please visit the Company’s website at www.clovisoncology.com

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