



Crizotinib Demonstrates Clinical Benefit in Phase II Study of East Asian Patients with ROS1-Positive Non-Small Cell Lung Cancer

Data to be Presented from largest ROS1-positive NSCLC cohort at 2016 ASCO Annual Meeting

CHICAGO, June 3, 2016 – OxOnc Development LP, (OxOnc), today announced that Study OO-1201, a Phase 2 open-label, single-arm study of crizotinib in East Asian patients with ROS1-positive metastatic non-small cell lung cancer (NSCLC), met its primary objective of demonstrating a high overall response rate for crizotinib. Study OO-1201 enrolled 127 ROS1-positive patients in the People’s Republic of China (PRC), Japan, Taiwan and South Korea, and is the largest ROS1-positive NSCLC cohort reported to date. The study will be presented as a Poster Discussion at the 2016 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago on Saturday, June 4, 2016.

Data from the study confirmed the clinical benefit of crizotinib in East Asian patients with ROS1-positive metastatic NSCLC with an objective response rate of 69 percent (95% CI, 61-77) by an independent radiology review. The safety profile of crizotinib in patients with ROS1-positive NSCLC was consistent with the known overall crizotinib safety profile.

“We are extremely pleased for the opportunity to collaborate with Pfizer on this important project. Patients with ROS1-positive metastatic NSCLC are in acute need of biomarker-driven treatment options, and the data collected from this trial in East Asian patients brings us one step closer to fulfilling that need. We want to thank the investigators, patients and other partners for their participation and support” said Wenn Sun, Ph.D., managing partner, OxOnc Development LP.

“The positive results from this study add to the growing body of data showing the benefit of crizotinib in patients with ROS1-positive metastatic NSCLC,” said Dr. Mace Rothenberg, chief medical officer, Pfizer Oncology and senior vice president, Global Product Development, Oncology. “Crizotinib is the first and only approved biomarker-driven therapy for ALK-positive

and ROS1-positive NSCLC in the U.S., and through our work with OxOnc, we look forward to unlocking the full potential of this therapy for patients.”

Recruitment for Study OO-1201 was conducted in collaboration with the Lung Cancer Genomic Screening Project in Japan and Chinese Thoracic Oncology Group in the PRC, two leading academic consortia in lung cancers and precision medicine. For the companion diagnostic development, OxOnc collaborated with Amoy Diagnostics and Riken Genesis in the PRC and Japan, respectively.

ROS1 rearrangements occur when the ROS1 gene attaches to another gene and changes the way each gene normally functions, which can contribute to cancer-cell growth. Epidemiology data suggest that ROS1 rearrangements occur in approximately 2.4 percent of Asian patients with NSCLC.¹ It is estimated that 1.5 million new cases of NSCLC will be diagnosed worldwide each year.^{2,3,4}

About OxOnc:

OxOnc Development LP is an oncology development company founded by pharmaceutical executives and oncology experts who previously held leadership positions at GSK, Sanofi and Quintiles, and has been funded by Orbimed Advisors, a leading venture capital group in life sciences. In December 2012, Pfizer and OxOnc entered into a co-development agreement pursuant to which OxOnc provided funding and execution for the ROS-1 study with the goal of generating the clinical data necessary for Pfizer to submit crizotinib ROS1 data for regulatory approvals in Asia.

For additional information:

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¹ Chen YF et al. Clinical and the prognostic characteristics of lung adenocarcinoma patients with ROS1 fusion in comparison with other driver mutations in East Asian populations. *J Thorac Oncol.* 2014 Aug;9(8):1171-9.

² Gainor JF, Shaw AT. Novel targets in non-small cell lung cancer: ROS1 and RET fusions. *Oncologist* 2013;18:865-75.

³ American Cancer Society. Detailed Guide: What is Lung Cancer – Non-Small Cell? Available at: <http://www.cancer.org/cancer/lungcancer-non-smallcell/detailedguide/non-small-cell-lung-cancer-what-is-non-small-cell-lung-cancer>. Accessed March 16, 2015.

⁴ World Health Organization. GLOBOCAN 2012: Estimated Cancer Incidence, Mortality and Prevalence Worldwide in 2012. Available at: http://globocan.iarc.fr/Pages/fact_sheets_cancer.aspx. Accessed December 29, 2015.