



## **OxOnc Announces Agreement With Pfizer to Develop Crizotinib as First-Line and Second-line Treatment for Patients With ROS1-Positive Non-Small Cell Lung Cancer**

Pivotal Trial to be Conducted in Four Asian Countries

**February, 8, 2013, Princeton, NJ-** OxOnc Development LP, (OxOnc), today announced that it has entered into a co-development agreement with Pfizer Inc., to conduct a pivotal clinical trial of Pfizer's crizotinib, marketed under the trademark Xalkori®, for the treatment of patients with advanced non-small cell lung cancer (NSCLC) harboring a ROS1 (c-ros) gene rearrangement (ROS1-positive). ROS1 is a receptor tyrosine kinase of the insulin receptor family.

The trial will be conducted at multiple sites in Japan, China, Taiwan and South Korea to assess the safety and efficacy of crizotinib in patients with ROS1-positive advanced NSCLC. Crizotinib is approved for the treatment of patients with ALK-positive advanced NSCLC in the U.S., EU<sup>1</sup>, Japan and other countries.

Under the terms of the agreement, OxOnc will provide funding and supervision for the trial, with the goal of generating the clinical data necessary for Pfizer to submit crizotinib for review by regulatory authorities for the treatment of advanced ROS1-positive NSCLC in the Asian region. If approved for this indication, OxOnc will be eligible to receive milestone payments from Pfizer. Additional terms were not disclosed.

"We are extremely pleased to collaborate with Pfizer and to support further clinical development of Xalkori® in NSCLC patients. It is gratifying to be involved in co-developing this innovative targeted therapy which exemplifies the future of oncology drug development," said Wenn Sun, Ph.D., OxOnc's Managing Partner.

"Pfizer continues to establish innovative partnerships that extend the scale and scope of our oncology clinical development program," said Garry Nicholson, president and general manager, Pfizer Oncology. "Xalkori® is a breakthrough medicine in our oncology portfolio which may hold potential for patients with ROS1-positive advanced NSCLC. Through our collaboration with OxOnc, we hope to explore the potential benefit that this important therapy may bring to this subset of lung cancer patients who are in need of additional treatment options."

### **About NSCLC and Crizotinib (Xalkori®):**

The understanding of lung cancer is changing. What was previously believed to be an illness largely linked to smoking is now recognized by physicians as a complex disease with many subtypes. NSCLC comprises approximately 85 percent of lung cancer cases. Research on the genetics of NSCLC is leading to an evolution in lung cancer treatment paradigms.



Xalkori® is a first-in-class, small molecule inhibitor of anaplastic lymphoma kinase (ALK), and is approved in the U.S., EU, Japan, China and other countries to treat patients with ALK-positive advanced NSCLC. In a Phase 1 clinical trial, Xalkori® demonstrated early signs of antitumor activity in a cohort of advanced NSCLC patients whose tumors have the ROS1 gene rearrangement.<sup>2</sup> Its activity in this patient population continues to be studied in other ongoing trials.<sup>3</sup>

**About OxOnc:**

OxOnc Development LP is an oncology development company founded by pharmaceutical development executives and oncology experts. OxOnc partners have extensive experience in building and managing oncology research networks in Europe and Asia and in managing global contract research organizations to optimally design and execute clinical trials. OxOnc is funded by Orbimed Advisors, a leading venture capital group in life sciences, with \$6 billion under management. MTS Securities, LLC acted as exclusive financial advisor to OxOnc on this transaction. Foley & Lardner LLP and WilmerHale acted as legal counsel in the transaction.

**For additional information:**

Wenn Sun, Ph.D.  
OxOnc Development LP  
T: 609.228.5757 ext: 102  
F: 609.935.0918  
Email: [Info@oxfordoncology.com](mailto:Info@oxfordoncology.com)

**Forward-Looking Information Statement**

This release contains forward-looking information about a potential additional indication for crizotinib, including its potential benefits, that involves substantial risks and uncertainties. Such risks and uncertainties include, among other things, the uncertainties inherent in research and development; whether and when any drug applications may be filed in any jurisdictions for such additional indication; whether and when any such applications may be approved by regulatory authorities, as well as their decisions regarding labeling and other matters that could affect its availability or commercial potential; and competitive developments.

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<sup>1</sup> Crizotinib (Xalkori®) has received conditional marketing authorization in the EU for the treatment of adults with previously treated ALK-positive advanced NSCLC.

<sup>2</sup> ASCO Accepted Abstract #7508. Clinical activity of crizotinib in advanced non-small cell lung cancer (NSCLC) harboring ROS1 gene rearrangement. Clinical Science Symposium. Alice T. Shaw. Saturday, June 2, 2012. 8:00 AM – 8:15 AM.



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<sup>3</sup> Clinicaltrials.gov. A Study Of Oral PF-02341066, A c-Met/Hepatocyte Growth Factor Tyrosine Kinase Inhibitor, In Patients With Advanced Cancer. Available at: <http://clinicaltrials.gov/ct2/show/NCT00585195>. Accessed February 1, 2013.