FDA Approval of XALKORI (crizotinib) and Invitation to Media Briefing from Pfizer

Monday, August 29, 2011 - 02:08am

(BUSINESS WIRE)--Pfizer Inc. has received FDA approval of XALKORI® (crizotinib) capsules – the first and only therapy specifically for patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) that is anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test. The effectiveness of XALKORI is based on objective response rates and, as XALKORI received accelerated approval from the FDA, Pfizer is conducting post-marketing clinical trials to further demonstrate its clinical benefit.*

On Tuesday, August 30 at 11:00 a.m. EST, Pfizer will convene a panel, including Pfizer Leadership, prominent lung cancer experts and patients who are treated with XALKORI, to discuss the implications of this important milestone for patients, oncologists and drug development at large. These panelists will be available for a Q&A session following opening remarks.

Geno Germano, Pfizer, President and General Manager, Specialty Care and Oncology – Pfizer’s business approach to cancer drug development Garry Nicholson, Pfizer, President and General Manager of the Pfizer Oncology Business Unit – Global collaboration to ensure commercial availability of XALKORI Mace Rothenberg, MD, Pfizer, Senior Vice President, Clinical Development, and Medical Affairs, Oncology Business Unit – XALKORI data and clinical development program; a biomarker-driven approach Paul A. Bunn, Jr., MD, Professor of Medicine and James Dudley Chair in Cancer Research, University of Colorado, Denver – Molecular perspective on XALKORI and the significance of molecular testing in lung cancer Mark G. Kris, MD, Chief, Thoracic Oncology Service, Memorial Sloan-Kettering Cancer Center, and Professor of Medicine, Weill Cornell Medical College – Clinical perspective on XALKORI and what this milestone means for patients Jeff Wigbels, Senior Vice President, Senior Portfolio Manager, Morgan Stanley Smith Barney, patient

with locally advanced or metastatic ALK-positive NSCLC who is being treated with XALKORI – Patient perspective on XALKORI and the importance of ALK testing Richard Heimler, former non-profit executive, patient with locally advanced or metastatic ALK-positive NSCLC who is being treated with XALKORI – Patient perspective on XALKORI and the importance of ALK testing

Please join the teleconference by dialing either 866 246-2545 in the United States and Canada, or 706 634-2365 outside of the United States and Canada. The passcode is “Pfizer FDA Approval”.

To view the press release, please visit www.pfizer.com.

For full prescribing information, go to www.xalkori.com.

*The FDA approved indication is based on response rate. There are no data available demonstrating improvement in patient reported outcomes or survival with XALKORI.

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