Pfizer Stops Clinical Trials of Thelin® and Initiates Voluntary Product Withdrawal in the Interest of Patient Safety

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(BUSINESS WIRE)--Pfizer Inc. (NYSE: PFE) announced today that, in the interest of patient safety, it is voluntarily withdrawing Thelin® (sitaxentan) for the treatment of pulmonary arterial hypertension (PAH) in regions where it is approved (the European Union, Canada and Australia). In addition, Pfizer is discontinuing clinical studies of Thelin worldwide.

Pfizer's decision was based on a review of emerging safety information from clinical trials and post-marketing reports. While liver toxicity is a known complication of the class of drugs to which Thelin belongs, a new potentially life-threatening idiosyncratic risk of liver injury with Thelin has been observed. Given the availability of alternate treatments, Pfizer has concluded that the overall benefit of Thelin no longer outweighs the risk in the general population of PAH patients. The Company has notified health authorities about this finding and its decision to voluntarily withdraw Thelin from the market and stop clinical studies.

"Pfizer's priority is to ensure the safety and well-being of patients, and we are in the process of communicating all of this information to the appropriate medical professionals and regulatory authorities in all regions as quickly as possible," said Cara Cassino, MD, vice president, Clinical Development and Medical Affairs for Pfizer's Pulmonary Vascular

Disease unit.

Pfizer recommends that no new patients be prescribed Thelin and that patients receiving Thelin be transitioned to appropriate alternate therapies as soon as safely possible according to best local practice. Patients taking Thelin or participating in Thelin studies are advised to consult with their health care professional as soon as possible. Patients should not stop taking Thelin until they speak to their health care professional.

For further information, contact the local Pfizer Country office. (Pfizer country websites can be accessed at http://www.pfizer.com/general/global_sites.jsp.)

Thelin is approved in the European Union, Australia and Canada to treat patients with pulmonary arterial hypertension. Pulmonary arterial hypertension is a rare, progressive, life-threatening disease that may result in heart failure and premature death. Pfizer remains committed to research in pulmonary vascular disease.

Prescribing information for Thelin from countries where it is currently approved is available at the following links:

-- Australia: http://www.pfizer.com.au/ProductInfo.aspx

-- Canada: http://www.pfizer.ca/en/our_products/products/product/170

-- European Union:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000679/hum

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