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MEDRx Co., Ltd.
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Stock code: 4586, TSE Mothers

Start of Clinical Trial of ETOREAT®

The MEDRx Group is currently working in the United States on the development of ETOREAT®, a topical patch for alleviating pain caused by inflammation. The outlook for the development schedule was announced on November 16, 2015 in a news release titled "Change in Schedule for the Development of ETOREAT®." We are also pleased to announce that clinical trials have started in the United States.

This clinical trial is for a disease model concerning delayed onset muscle soreness (DOMS), which is one type of acute pain as agreed upon with the FDA. The trial will induce DOMS in about 100 healthy test subjects by artificially creating stress on muscles. The effectiveness of ETOREAT® will then be checked by monitoring any reduction in pain.

Last patient out is scheduled to be completed by June 2016 and the flash report of trial is expected to be available from July to August 2016.

No changes are expected in the development schedule of ETOREAT®. (The flash report of second trial: Second half of 2016; NDA submission to the FDA: First half of 2017)

The impact of the start of clinical trials has already been incorporated in the 2016 forecast.

<Reference>
ETOREAT®, a topical patch that incorporates etodolac*, is the most important item in the MEDRx Group’s pipeline. This is expected to be the first finished product that uses the MEDRx ILTS® (Ionic Liquid Transdermal System). Development activities are proceeding in the United States with the goal of receiving approval to manufacture and sell ETOREAT® as a prescription drug.
*Etodolac is a non-steroidal anti-inflammatory drug (NSAID) that is used extensively worldwide as an oral treatment for pain and inflammation. MEDRx's ETOREAT® is the world's first attempt to develop a version for use as a patch.

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