Phase I Clinical Trial Results for MRX-5LBT in the United States

The MEDRx Group is currently working in the United States on the development of MRX-5LBT, a medicated patch with lidocaine*1 for alleviating nerve pain associated with shingles. In the previous release titled "Start of MRX-5LBT Clinical Trial in the United States" dated March 25, 2016, clinical trials have started in the United States. We are pleased to announce the phase I clinical trial results.

MRX-5LBT is a new type of lidocaine patch that uses the ILTS® (Ionic Liquid Transdermal System), an exclusive MEDRx technology that incorporates the company's ionic liquid*2 expertise. MRX-5LBT is being developed with the goal of targeting the Lidoderm®, a lidocaine patch, market that at one time had annual U.S. sales equivalent to 120 billion yen and to further expand sales. Test results seem to indicate that MRX-5LBT allows lidocaine to penetrate the skin faster than Lidoderm®, confirming the superiority of the ILTS® technology.

The MEDRx Group is putting renewed focus on clinical development activities with the goal of NDA submission for MRX-5LBT quickly. Information about these activities and the projected timetable cannot be disclosed for competitive reasons.

This result will have no impact on the consolidated results of operations in 2016.

<Reference>
*1 Lidocaine
Lidocaine is a type of local anesthetic that reduces pain by blocking the transmission of pain signals at the ends of nerves.

*2 Ionic liquid
An ionic liquid is a salt with a melting point of not more than 100°C and is also called a room temperature molten salt. Properties include a low melting point, high ion conductivity, high polarity, non-volatility and non-combustibility. Many applications are being examined for ionic liquids, including in solar cells and environmentally responsible reaction solvents. MEDRx was first in the world to discover that converting drugs into ionic liquids and dissolving drugs in ionic liquids can dramatically increase the transdermal permeability of these drugs. MEDRx has gained considerable knowledge involving ionic liquids. There is a library of ionic liquids that are believed to be safe by combining them with compounds that have already been used for human consumption. MEDRx has expertise in selecting ionic liquids that are best suited to increasing the transdermal permeability of targeted drugs. And MEDRx has the know-how to produce drugs in format that is easy to use (patches, ointments, etc.) while retaining the properties of ionic liquids that contain drugs. The exclusive technology for producing transdermal drugs, which incorporates this knowledge, is called the Ionic Liquid Transdermal System (ILTS®).
Summary of MRX-5LBT Phase 1 study

- The following points of MRX-5LBT were suggested by our Phase 1 study which compared MRX-5LBT with Lidoderm®, which is already commercialized in US.

  1. Skin absorption speed of MRX-5LBT is faster than of Lidoderm®. (Fig.1)

  2. Lidocaine volume per unit area of MRX-5LBT is estimated approximately 2.6 times one of Lidoderm® at the subcutaneous tissue because MRX-5LBT is a half size of Lidoderm®. (Fig.2)

Fig.1 Transition of Lidocaine in human blood between MRX-5LBT and Lidoderm®

Fig.2 Cumulative volume per unit area of Lidocaine between MRX-5LBT and Lidoderm® under human skin tissue (Estimated from Fig.1)