



**News Release Dated November 10, 2021**

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

## **U.S. Investigational New Drug Application Submitted for MRX-7MLL**

MEDRx USA Inc., a wholly owned subsidiary of MEDRx Co., Ltd., has filed an investigational new drug (IND) application with the U.S. Food and Drug Administration (FDA) for MRX-7MLL. Used to treat Alzheimer's disease, MRX-7MLL is a patch that uses NCTS®\*1 (Nano-sized Colloid Transdermal System), an exclusive MEDRx transdermal absorption technology, and contains memantine\*2.

In 2020, sales of drugs for Alzheimer's disease generated sales of about \$475 million in the United States. Oral memantine drugs account for about \$106 million of these sales (source: IQVIA). Oral drugs are taken once every day. A patch needs to be replaced only once every three days to one week and the administration of a drug using a patch can be visually confirmed easily by patients, family members and healthcare professionals. Providing the option of using a patch is therefore expected to improve the quality of life of family and professional caregivers as well as individuals with Alzheimer's disease. Patches will also help increase the reliability of administering drugs, such as by eliminating the risk of someone forgetting to take a pill.

At the pre-IND meeting with the FDA, the MEDRx Group confirmed that there will be no need for phase II and III clinical trials to demonstrate the efficacy of MRX-7MLL if MRX-7MLL can be shown to be biologically equivalent to oral drugs containing memantine. Consequently, MEDRx believes that a new drug application for MRX-7MLL can be submitted quickly.

There is no impact on our 2021 results of operations in association with this matter.

### **<Reference>**

#### **\*1 NCTS® (Nano-sized Colloid Transdermal System)**

A colloid is a state in which one substance is dispersed in the form of microscopic droplets or microscopic particles through another substance. A nano-colloid has nano-scale droplets or particles. MEDRx discovered that the use of a nano-sized colloid increases the ability of the skin to absorb a drug and lowers side effects. MEDRx named this technology the NCTS® (Nano-sized Colloid Transdermal System).

#### **\*2 Memantine**

Memantine is an NMDA receptor antagonist that suppresses excessive glutamic acid activity in the brain in order to protect nerve cells and allow proper neural transmission. The substance slows the progression of medium to severe Alzheimer's dementia.

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