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FDA Acceptance of New Drug Application for DW-5LBT

D. Western Therapeutics Institute, Inc. (“DWTI”) are pleased to announce that the U.S. Food and Drug Administration (FDA) has accepted the New Drug Application (NDA) for DW-5LBT (Lidocaine (Note 1) patch; brand name: Lydolyte), the treatment of post-herpetic neuralgia.

DW-5LBT has being co-developed in the United States by DWTI and MEDRx, Co., Ltd. (“MEDRx”), and the NDA had been resubmitted to the FDA on March 25, 2025.

This acceptance of the NDA means that the FDA has confirmed that the documents pertaining to the application are sufficiently complete during the post-submission review period and has begun a full-scale review. The target action date under the Prescription Drug User Fee Act (PDUFA) is September 24, 2025.

The acceptance of this NDA will have no impact on the forecast for the fiscal year ending December 2025, but is expected to contribute to the improvement of earnings over the medium to long term.

DW-5LBT (MEDRx development code: MRX-5LBT)

DW-5LBT is a novel lidocaine patch that utilizes MEDRx’s proprietary ionic liquid transdermal system (ILTS®) technology and is being developed to address and expand the existing market for the Lidoderm® lidocaine patch. Based on the results of the clinical trials to date, DW-5LBT is expected to penetrate the market as a superior product to Lidoderm®, the leading benchmark product, with less skin irritation, superior adhesive strength, and retention of adhesive strength even during exercise. The US market for lidocaine patch products was estimated to be worth about USD 193 million in 2023.

Explanation of terms

(Note 1) Lidocaine
Lidocaine is a local anesthetic that reduces pain by blocking pain signals at nerve endings.

(Note 2) Prescription Drug User Fee Act
A law introduced in the U.S. in 1992 that requires the collection of drug review fees from sponsors (pharmaceutical companies) as an applicant fee to cover the cost of review. The purpose of this law is to facilitate approval review and shorten the review period by imposing deadlines on the FDA's review of drug approval.