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To whom it may concern:

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Change of Proprietary Name for DW-5LBT

The U.S. Food and Drug Administration (FDA) has conditionally accepted the new proprietary name "Bondlido" for DW-5LBT, a medicated patch with lidocaine (Note 1) which D. Western Therapeutics Institute, Inc. and the MEDRx Group are jointly developing in the United States.

The proprietary name "Lydolyte" which had been provisionally approved until now, was requested to be changed by the FDA, which stated that "it is highly similar to the name of an existing product and there is a certain degree of possibility of it being misused." The new proprietary name "Bondlido" has been submitted and approved conditionally from the FDA.

The new proprietary name "Bondlido" will be officially approved if the DW-5LBT New Drug Application which has a Prescription Drug User Fee Act target date of September 24, 2025 is approved.

This change of proprietary name for DW-5LBT will have no effect on the forecast for the fiscal year ending December 31, 2025.

DW-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 162 million in 2024 (date source : MEDRx).

End

Explanation of terms

(Note 1) Lidocaine

Lidocaine is a local anesthetic that reduces pain by blocking pain signals at nerve endings.