Endo Pharmaceuticals Announces Receipt of Paragraph IV Certification

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CHADDS FORD, Pa., Jan. 31, 2011 /PRNewswire/ -- Endo Pharmaceuticals (Nasdaq: ENDP [1]) announced today that its partners, Teikoku Seiyaku Co., Ltd. and Teikoku Pharma USA, Inc., have received a Paragraph IV Certification Notice from Mylan Technologies Inc. advising of the filing of an Abbreviated New Drug Application (ANDA) for a generic version of LIDODERM® (lidocaine topical patch 5%).

The company is currently reviewing the details of this notice from Mylan. Endo intends to vigorously defend LIDODERM's intellectual property rights and will pursue all available legal and regulatory pathways in defense of LIDODERM.

The Paragraph IV certification notice refers to U.S. Patent Nos. 5,741,510 and 5,827,529, which cover the formulation of LIDODERM, a topical patch to relieve the pain of postherpetic neuralgia launched in 1999. These patents are listed in the U.S. Food and Drug Administration's (FDA) Orange Book and expire in March 2014 and October 2015, respectively.

Citizen Petition

With respect to Endo's regulatory approach, the company submitted a Citizen Petition in 2006 in reaction to a proposal by FDA's Office of Generic Drugs that would diverge from applicable regulations and standards of practice regarding bioequivalence. The company is requesting that the agency reconsider its departure from its longstanding general rule of requiring clinical endpoint bioequivalence studies for locally acting topical generic drug products, including those that reference LIDODERM. To ensure the safe and effective equivalence of any generic version to LIDODERM, which acts locally in the skin, Endo believes that FDA must return to its established standard of clinical endpoint bioequivalence studies.

About Endo

Endo Pharmaceuticals is a U.S.-based, specialty healthcare solutions company, focused on high-value branded products and sp
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