

Zydus Pharmaceuticals (USA) Inc agreement with Warner Chilcott Company LLC

December 11, 2013

Cadila Healthcare Limited, a global pharmaceuticals company, and Zydus Pharmaceuticals (USA), Inc., a leading generic pharmaceutical company in the United States, today announced that they have entered into an agreement in principle with Warner Chilcott Company LLC to settle all outstanding patent litigation related to Asacol® HD (mesalamine) delayed-release tablets. The agreement remains subject to preparation and execution of definitive documentation.

Under the terms of the agreement in principle, Warner Chilcott Company will grant Cadila and Zydus a royalty-bearing license to market a generic version of Asacol® HD beginning on November 15, 2015 or earlier under certain circumstances, following receipt by Zydus of final approval from the U.S. Food and Drug Administration (FDA) of its Abbreviated New Drug Application (ANDA) for generic Asacol® HD.

Alternatively, if Zydus does not receive FDA approval of its generic Asacol® HD by July 1, 2016, Zydus will be permitted to launch an authorized generic version of Asacol® HD beginning on July 1, 2016. Other terms of the settlement were not disclosed.

About Zydus Cadila

Zydus Cadila is an innovative, global pharmaceutical company that discovers, develops, manufactures and markets a broad range of healthcare therapies. The group employs over 15,000 people worldwide and is dedicated to creating healthier communities globally. Zydus Cadila is the only Indian pharma company to launch its own patented NCE – Lipaglyn™, the world's first drug to be approved for the treatment of diabetic dyslipidemia. It aims to be a leading global healthcare provider with a robust product pipeline, achieve sales of over \$3 billion by 2015 and be a research-based pharmaceutical company by 2020.
