Glenmark
A new way for a new world

December 12, 2016

The Dy. General Manager
Dept. of Corporate Affairs
The Bombay Stock Exchange Ltd,
Phiroze Jeejeebhoy Towers
Dalal Street
Mumbai: 400001

Dear Sir,

We are enclosing herewith press release informing **"Glenmark Launches First and Only Generic Version of Zetia® in the United States"** for your information and record.

Thanking you.

Yours faithfully,
For Glenmark Pharmaceuticals Ltd.

Cherylann Pinto
Director – Corporate Affairs

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Encl: as above

Press Release **For Immediate Dissemination**

Glenmark Launches First and Only Generic Version of Zetia® in the United States

Mumbai, India; December 12, 2016: Glenmark Pharmaceuticals Inc., USA today announced the availability of ezetimibe, the first and only generic version of ZETIA® (Merck) in the United States for the treatment of high cholesterol. The availability of ezetimibe is the result of a licensing partnership with Par Pharmaceutical, an Endo International plc operating company, with whom Glenmark will share profits. Glenmark and its partner, Endo will be entitled to 180 days of generic drug exclusivity for ezetimibe as provided for under section 505(j)(5)(B)(iv) of the FD&C Act.

Ezetimibe is indicated as adjunctive therapy to diet for the reduction of elevated total cholesterol (total-C), low-density lipoprotein cholesterol (LDL-C), and apolipoprotein B (Apo B) in patients with primary (heterozygous familial and non-familial) hyperlipidemia.

According to IMS Health data for the 12-month period ending October 2016, annual U.S. sales of Zetia® 10 mg[1] were approximately $2.3 billion[2].

"Glenmark has a deep heritage of bringing safe, effective and affordable medicines to patients around the world," said Robert Matsuk, President of North America and Global API at Glenmark Pharmaceuticals Ltd. "Our partnership with Par to bring the first generic version of ZETIA® to market only underscores our joint commitment to bridging the gap between patients and the medicines they need most."

"We, along with our partners at Glenmark, are proud to be able to offer patients managing their cholesterol levels the first generic version of ZETIA®," said Tony Pera, President of Par Pharmaceutical. "Par remains committed to providing patients access to high quality and affordable medicines."

Glenmark's current portfolio consists of 111 products authorized for distribution in the U.S. marketplace and 64 ANDA's pending approval with the U.S. Food and Drug Administration. In addition to these internal filings, Glenmark continues to identify and explore external development partnerships to supplement and accelerate the growth of its existing pipeline and portfolio.

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[1] Market includes brand all available therapeutic equivalents

[2] IMS Health National Sales Perspectives: Retail & Non-Retail, October 2016.

Important Safety Information

Ezetimibe is a prescription medicine and should not be taken by people who are allergic to any of its ingredients. Ezetimibe can be taken alone or with a statin. Statins should not be taken by women who are nursing or pregnant or who may become pregnant, or by anyone with liver problems. If you have ever had liver problems or are pregnant or nursing, your doctor will decide if ezetimibe alone is right for you. Your doctor may do blood tests to check your liver before you start taking ezetimibe with a statin and during treatment.

Concurrent administration of ezetimibe with a specific statin or fenofibrate should be in accordance with the product labeling for that medication.

Ezetimibe initiated concurrently with a statin, the incidence of consecutive elevations (≥3 × ULN) in hepatic transaminase levels was 1.3% for patients treated with ezetimibe administered with statins and 0.4% for patients treated with statins alone When ezetimibe is co-administered with a statin, liver tests should be performed at initiation of therapy and according to the recommendations of the statin.

Risk for skeletal muscle toxicity increases with higher doses of statin, advanced age (>65), hypothyroidism, renal impairment, and depending on the statin used, concomitant use of other drugs. Ezetimibe and any statin or fibrate that the patient is taking concomitantly should be immediately discontinued if myopathy is diagnosed or suspected.

Due to the unknown effects of the increased exposure to ezetimibe in patients with moderate to severe hepatic impairment, ezetimibe is not recommended in these patients. Cyclosporine concentrations should be monitored in patients receiving ezetimibe and cyclosporine.

The efficacy and safety of co-administration of ezetimibe with fibrates other than fenofibrate have not been studied.

The most common adverse reactions in the group of patients treated with ezetimibe were: Arthralgia, Dizziness, Gamma-glutamyltransferase increased, upper respiratory tract infection, diarrhea, sinusitis and pain in extremity.

The most common adverse reactions in the group of patients treated with ezetimibe + statin were: alanine aminotransferase increased, myalgia, fatigue, aspartate aminotransferase increased, headache, pain in extremity.

About Glenmark Pharmaceuticals Ltd.:

Glenmark Pharmaceuticals Ltd. (GPL) is a research-driven, global, integrated pharmaceutical organization headquartered at Mumbai, India. It is ranked among the top 80 Pharma & Biotech companies of the world in terms of revenue (SCRIP 100 Rankings published in the year 2016). Glenmark is a leading player in the discovery of new molecules both NCEs (new chemical entity) and NBEs (new biological entity). Glenmark has several molecules in various stages of clinical development and is primarily focused in the areas of Inflammation [asthma/COPD, rheumatoid arthritis etc.] and Pain [neuropathic pain and inflammatory pain]. The company has a significant presence in the branded generics markets across emerging economies including India. GPL along with its subsidiaries operate 17 manufacturing facilities across four countries and has five R&D centers. The Generics business of Glenmark services the requirements of the US and Western European markets. The API business sells its products in over 80 countries including the US, EU, South America and India.

About Endo International plc:

Endo International plc (NASDAQ / TSX: ENDP) is a global specialty pharmaceutical company focused on improving patients' lives while creating shareholder value. Endo develops, manufactures, markets and distributes quality branded and generic pharmaceutical products as well as over-the-counter medications though its operating companies. Endo has global headquarters in Dublin, Ireland, and U.S. headquarters in Malvern, PA. Learn more at www.endo.com.

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