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## **Horizon Pharma plc Announces District Court Decision to Uphold VIMOVO® (naproxen/esomeprazole magnesium) Patents**

### **Patents Covering VIMOVO Infringed by Proposed Generics Developed by Dr. Reddy's Laboratories, Mylan, and Lupin**

DUBLIN, Ireland, June 27, 2017 (GLOBE NEWSWIRE) -- Horizon Pharma plc (NASDAQ:HZNP), a biopharmaceutical company focused on improving patients' lives by identifying, developing, acquiring and commercializing differentiated and accessible medicines that address unmet medical needs, today announced that the United States District Court for the District of New Jersey upheld the validity of two Horizon Pharma patents covering VIMOVO® (naproxen/esomeprazole magnesium), and that Dr. Reddy's Laboratories Inc. and Dr. Reddy's Laboratories Ltd. ("Dr. Reddy's"), Mylan Pharmaceuticals Inc., Mylan Laboratories Ltd., and Mylan Inc. ("Mylan"), and Lupin Ltd. and Lupin Pharmaceuticals Inc. ("Lupin") would infringe at least one of the two patents with their proposed generic naproxen/esomeprazole magnesium products.

On April 21, 2011, July 25, 2011, and June 28, 2013, Horizon filed patent infringement lawsuits in District Court against Dr. Reddy's, Lupin, and Mylan, respectively, related to Abbreviated New Drug Applications filed with the U.S. Food and Drug Administration to market generic versions of VIMOVO. The lawsuits claim infringement of Horizon's U.S. Patent Nos. 8,557,285 ('285 patent) and 6,926,907 ('907 patent) titled "Pharmaceutical Compositions for the Coordinated Delivery of NSAIDs," which cover VIMOVO. The District Court's decision was made based on the validity of Horizon Pharma's '285 and '907 patents for VIMOVO and the Court's judgment will prevent Dr. Reddy's, Mylan, and Lupin from launching generic versions of VIMOVO in the United States.

VIMOVO has 14 Orange Book listed patents with terms that extend to 2031. The '285 patent expires in May 2022 and the '907 patent expires in February 2023.

#### **About VIMOVO**

VIMOVO (naproxen/esomeprazole magnesium) is a fixed-dose combination of delayed-release enteric-coated naproxen, a non-steroidal anti-inflammatory drug (NSAID), and immediate-release esomeprazole magnesium, a stomach acid-reducing proton pump inhibitor (PPI), approved for the relief of signs and symptoms of osteoarthritis, rheumatoid arthritis and ankylosing spondylitis and to decrease the risk of developing gastric ulcers in patients at risk of developing NSAID-associated gastric ulcers. VIMOVO is not interchangeable with the individual components of naproxen and esomeprazole magnesium.

VIMOVO is not recommended for use in children younger than 18 years of age. VIMOVO is not recommended for initial treatment of acute pain because the absorption of naproxen is delayed compared to absorption from other naproxen-containing products. Controlled studies do not extend beyond six months. VIMOVO should be used at the lowest dose and for the shortest amount of time as directed by your health care provider. For Full Prescribing Information please see [www.VIMOVO.com](http://www.VIMOVO.com).

#### **Important Safety Information**

- ▮ **Nonsteroidal anti-inflammatory drugs (NSAIDs), including naproxen, a component of VIMOVO, may increase the chance of a heart attack or stroke, which can be fatal. This chance increases with longer use and in people who have heart disease or risk factors for heart disease.**
- ▮ **VIMOVO should not be used before or after a type of heart surgery called coronary artery bypass graft (CABG).**
- ▮ **NSAID-containing medications like VIMOVO may increase the chance of stomach and intestinal problems, such as bleeding or an ulcer. These problems can happen without warning and can lead to death. Older patients may have a greater chance of developing these problems.**

VIMOVO is not right for everyone, including patients who have had an asthma attack, hives or other allergic reaction with aspirin or any other NSAID medicine, patients who are allergic to any of the ingredients in VIMOVO or women in late stages of pregnancy.

Serious allergic reactions, including skin reactions, can occur without warning and can be life-threatening; discontinue use of VIMOVO at the first appearance of a skin rash or if you develop sudden wheezing; swelling of the lips, tongue or throat; fainting or problems swallowing.

VIMOVO should be used at the lowest dose and for the shortest amount of time as directed by your health care provider.

Tell your health care provider right away if you develop signs of active bleeding from any source.

VIMOVO can lead to onset of new hypertension or worsening of existing high blood pressure, either of which may contribute to an increased risk of a heart attack or stroke.

Speak with your health care provider before starting VIMOVO if you

- | Have a history of ulcers or bleeding in the stomach or intestines
- | Have heart problems, high blood pressure, or are taking high blood pressure medications
- | Have kidney or liver problems

Tell your doctor about all of the medicines you take, prescription and non-prescription drugs, including clopidogrel, vitamins and herbal supplements. VIMOVO may affect how other medicines work and other medicines may affect how VIMOVO works.

VIMOVO may increase your risk of getting severe diarrhea. Call your doctor right away if you have watery stool, stomach pain and fever that does not go away.

Talk to your health care provider about your risk for bone fractures and developing low levels of magnesium if you take VIMOVO for a long period of time.

Talk to your health care provider about your risk for developing low levels of magnesium if you take VIMOVO for a long period of time.

The most common side effects of VIMOVO include: inflammation of the lining of the stomach, indigestion, diarrhea, stomach ulcers, abdominal pain and nausea.

For more information on VIMOVO, please see the [Medication Guide](#) and [Full Prescribing Information](#).

#### ***About Horizon Pharma plc***

Horizon Pharma plc is a biopharmaceutical company focused on improving patients' lives by identifying, developing, acquiring and commercializing differentiated and accessible medicines that address unmet medical needs. The Company markets 11 medicines through its orphan, rheumatology and primary care business units. For more information, please visit [www.horizonpharma.com](http://www.horizonpharma.com). Follow [@HZNPplc](#) on Twitter or view careers on our [LinkedIn](#) page.

#### ***Forward-Looking Statements***

This press release contains forward-looking statements, including statements regarding the impact of the District Court's ruling on Horizon Pharma's '907 and '285 patents. These forward-looking statements are based on management expectations and assumptions as of the date of this press release, and actual results may differ materially from those in these forward-looking statements as a result of various factors. These factors include risks regarding whether the defendants appeal the District Court's decision and whether the decision is upheld on such an appeal and other factors described in Horizon Pharma's filings with the United States Securities and Exchange Commission, including those factors discussed under the caption "Risk Factors" in those filings. Forward-looking statements speak only as of the date of this press release and Horizon Pharma does not undertake any obligation to update or revise these statements, except as may be required by law.

Contacts:

Tina Ventura

Senior Vice President, Investor Relations

[Investor-relations@horizonpharma.com](mailto:Investor-relations@horizonpharma.com)

Ruth Venning

Executive Director, Investor Relations

[Investor-relations@horizonpharma.com](mailto:Investor-relations@horizonpharma.com)

U.S. Media Contacts:

Geoff Curtis

Senior Vice President, Corporate Affairs and Chief Communications Officer

[media@horizonpharma.com](mailto:media@horizonpharma.com)

Ireland Media Contact:

Ray Gordon

Gordon MRM

[ray@gordonmrm.ie](mailto:ray@gordonmrm.ie)

 Primary Logo

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