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Horizon Pharma plc Announces District Court Decision to Uphold PENNSAID® (diclofenac sodium topical solution) 2% w/w Patent

Patent Covering PENNSAID® 2% Infringed by a Proposed Generic Developed by Actavis Laboratories UT, Inc.

DUBLIN, Ireland, May 15, 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 Horizon Pharma's patent covering PENNSAID® (diclofenac sodium topical solution) 2% w/w, which Actavis Laboratories UT, Inc. (Actavis) has admitted that its proposed generic diclofenac sodium topical solution product would infringe.

On July 6, 2015, Horizon filed a patent infringement lawsuit in District Court against Actavis related to Abbreviated New Drug Applications filed with the U.S. Food and Drug Administration to market a generic version of PENNSAID 2%. The lawsuit claims infringement of Horizon's U.S. Patent No. 9,066,913 (‘913 patent) titled "Diclofenac Topical Formulation," which covers PENNSAID 2%. The District Court's decision was made based on the validity of Horizon Pharma's ‘913 patent for PENNSAID 2% and the Court's judgment will prevent Actavis from launching a generic version of PENNSAID 2% in the United States.

PENNSAID 2% has 18 Orange Book listed patents with terms that extend to 2030.

About PENNSAID 2%
PENNSAID (diclofenac sodium topical solution) 2% w/w is a non-steroidal anti-inflammatory drug (NSAID) indicated for the treatment of pain of osteoarthritis (OA) of the knee(s). PENNSAID 2% contains diclofenac sodium, an NSAID, and also includes dimethyl sulfoxide (DMSO), a powerful penetrating agent that helps ensure that diclofenac sodium is absorbed through the skin to the site of inflammation and pain. PENNSAID 2% is an alternative to oral NSAID treatment, reducing systemic exposure to a fraction of that provided by the oral NSAID diclofenac. The only topical NSAID offered with the convenience of a metered-dose pump, PENNSAID 2% is applied in two pumps, twice daily, to the site of OA knee pain. For more information, please see ***www.PENNSAID.com.***

IMPORTANT SAFETY INFORMATION

WARNING: CARDIOVASCULAR AND GASTROINTESTINAL RISK

Heart Risk

- ***Non-steroidal anti-inflammatory drugs (NSAIDs) may cause an increased risk of serious heart clotting events, heart attack and stroke, which can kill you. This risk may increase with longer use. Patients with heart disease or risk factors for heart disease may be at greater risk.***
- ***PENNSAID 2% should not be used if you are in the hospital for certain heart surgeries.***

Stomach and Intestine Risk

- ***NSAIDs cause an increased risk of serious stomach and intestine events including bleeding, ulcers and holes in the stomach or intestines, which can kill you. These events can occur at any time during use and without warning symptoms. Elderly patients are at greater risk for serious stomach and intestine events.***

CONTRAINDICATIONS

- DO NOT USE PENNSAID 2% if you:
  - are in the hospital for certain heart surgeries.

- know you are allergic to diclofenac sodium or any other ingredient of PENNSAID 2%.

- have experienced asthma, hives, or allergic-type reactions after taking aspirin or other NSAIDs. Severe, allergic reactions that will rarely kill you, to NSAIDs have been reported in such patients.

WARNINGS AND PRECAUTIONS

- To minimize the potential for increased risk of serious heart events while being treated with an NSAID, use the lowest effective dose for the shortest duration possible.

- Elevation of one or more liver tests may occur during therapy with NSAIDs. PENNSAID 2% should be discontinued immediately if abnormal liver tests persist or worsen.

- Use with caution in patients with fluid retention or heart failure.

- Hypertension can occur with NSAID treatment. Monitor blood pressure closely with PENNSAID 2% treatment.

- Long-term use of NSAIDs can result in severe kidney injury. Use PENNSAID 2% with caution in patients at greatest risk of this reaction, including the elderly, those with impaired kidney function, heart failure, liver dysfunction and those taking diuretics and ACE-inhibitors (certain blood pressure medicines).

- Severe allergic reactions may occur without prior use of PENNSAID 2%. NSAIDs can cause serious skin reactions such as exfoliative dermatitis, Stevens-Johnson Syndrome (SJS) and toxic epidermal necrolysis (TEN), which can kill you.

- Wash and dry hands before and after use. Avoid contact of PENNSAID 2% with the eyes, nose and mouth.

- PENNSAID 2% was not studied under the conditions of heat application, complete covering bandages or exercise; therefore, concurrent use of PENNSAID under these conditions is not recommended.

- Do not:

  - Apply PENNSAID 2% to open wounds.

  - Shower for at least 30 minutes after applying PENNSAID 2%.

  - Wear clothing over the PENNSAID 2% treated knee until the treated knee is dry.

- Protect treated knee(s) from natural or artificial sunlight.

- Protect treated knee(s) from sunlight (real and tanning booths).

- Topicals, such as sunscreen and bug repellent, should not be used until after PENNSAID 2% treated knee(s) are completely dry.

- Do not use with oral NSAIDs unless your doctor says it is OK and you have lab tests to check your progress.

- There is no consistent evidence that regular use of aspirin lessens the increased risk of serious heart events, such as heart clotting, heart attack and stroke associated with NSAID use. As with all NSAIDs, regular administration of PENNSAID 2% and aspirin is not generally recommended because of the potential of increased risks.

ADVERSE REACTIONS

- The most common adverse events in a phase 2 clinical trial of PENNSAID 2% were application site reactions, such as dryness (22%), peeling (7%), redness (4%), itching (2%), pain (2%), skin hardening (2%), rash (2%) and scabbing (< 1%). Other adverse reactions occurring in > 1% of patients receiving PENNSAID 2% included bladder infection (3%), bruising (2%), sinus congestion (2%) and nausea (2%).

USE IN SPECIFIC POPULATIONS

- PENNSAID 2% should not be used in pregnant women or in women who are breastfeeding and is not approved for use in children.

For more information on PENNSAID 2%, please see the Medication Guide and Full Prescribing Information, available at *www.PENNSAID.com*.

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. 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 '913 patent. 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 Actavis appeals 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.

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