



December 24, 2014

Horizon Pharma plc Files Patent Infringement Lawsuit Against Watson Laboratories, Inc. for Filing an ANDA Against PENNSAID(R) 2%

DUBLIN, IRELAND -- (Marketwired) -- 12/24/14 -- Horizon Pharma plc (NASDAQ: HZNP), a specialty biopharmaceutical company with a portfolio of products in arthritis, inflammation and orphan diseases, announced today that the Company has filed a patent infringement lawsuit in the United States District Court for the District of New Jersey against Watson Laboratories, Inc. ("WLF") and certain of its affiliated companies, Actavis, plc, and Actavis Inc., related to an Abbreviated New Drug Application ("ANDA") that WLF filed with the U.S. Food and Drug Administration ("FDA") to market a generic version of PENNSAID® (diclofenac sodium topical solution) 2% w/w ("PENNSAID 2%").

The lawsuit claims infringement of U.S. Patent Nos. 8,217,078; 8,252,832; 8,546,450; 8,563,613; 8,618,614; and 8,871,809 that are listed in the FDA's Orange Book with the latest patent term expiring on August 9, 2030. Horizon Pharma received a Paragraph IV Patent Certification from WLF on November 13, 2014, advising that WLF had filed an ANDA with the FDA for a generic version of PENNSAID 2%. WLF alleged that its generic version of PENNSAID 2% would not infringe the subject U.S. patents or the patents are invalid or unenforceable. WLF has not advised Horizon as to the timing or status of the FDA's review of its filing, or whether it has complied with FDA requirements for providing bioequivalence.

Horizon Pharma commenced the lawsuit within the 45 days required to automatically stay, or bar, the FDA from approving WLF's ANDA for 30 months or until a district court decision that is adverse to the subject patents, whichever may occur earlier.

About Horizon Pharma plc

Horizon Pharma plc is a specialty biopharmaceutical company focused on improving patients' lives by identifying, developing, acquiring and commercializing differentiated products that address unmet medical needs. The Company markets a portfolio of products in arthritis, inflammation and orphan diseases. Horizon's U.S. marketed products are ACTIMMUNE® (interferon gamma-1b), DUEXIS® (ibuprofen/famotidine), RAYOS® (prednisone) delayed-release tablets and VIMOVO® (naproxen/esomeprazole magnesium). Beginning in January 2015, the Company expects to begin marketing PENNSAID® (diclofenac sodium topical solution) 2% w/w in the United States. Horizon's global headquarters are in Dublin, Ireland.

For more information, please visit www.horizonpharma.com.

Media and Investor Contact:

Elizabeth M. Higashi, CFA
Vice President, Investor Relations

[Email Contact](#)

+1 224 383-3285

Source: Horizon Pharma plc

News Provided by Acquire Media