Horizon Pharma plc Announces Clinical Data on RAYOS(R) (Prednisone) Delayed-Release Tablets and VIMOVO(R) (Naproxen/Esomeprazole Magnesium) to Be Presented at the American College of Rheumatology Annual Meeting

DUBLIN, IRELAND -- (Marketwired) -- 11/12/14 -- Horizon Pharma plc (NASDAQ: HZNP) today announced that four abstracts related to RAYOS (prednisone) delayed-release tablets and one abstract on VIMOVO (naproxen/esomeprazole magnesium) will be presented during the American College of Rheumatology (ACR) and Association of Rheumatology Health Professionals (ARHP) Annual Scientific Meeting taking place November 15 to 19, 2014 in Boston, MA.

RAYOS is the first and only delayed-release prednisone for the treatment of rheumatologic diseases such as rheumatoid arthritis and polymyalgia rheumatica. Horizon, in partnership with the Consortium of Rheumatology Researchers of North America, Inc. (CORRONA), and independent academic CORRONA researchers, developed the following three studies using the CORRONA Rheumatoid Arthritis patient registry consisting of over 35,000 patients:

**Title:** Prevalence of Morning Stiffness in a U.S. Registry Population of Rheumatoid Arthritis Patients  
**Authors:** Vibeke Strand, Robert J. Holt, Katherine C. Saunders, Jeffrey D. Kent, Ping Xu, Amy Y. Grahn, Marc Mason, Carol J. Etzel  
**Location:** Exhibit Hall B  
**Abstract #:** 418  
**Session:** ACR Poster Session A  
**Date:** Sunday, November 16, 2014  
**Time:** 9:00 to 11:00 AM ET


**Title:** Characteristics of Rheumatoid Arthritis Patients Not Receiving Early Initiation of Disease Modifying Therapy  
**Authors:** Dimitrios A. Pappas, Jeffrey D. Kent, Jeffrey D. Greenberg, Marc Mason Joel M. Kremer, Amy Y. Grahn, Robert J. Holt  
**Location:** Exhibit Hall B  
**Abstract #:** 2415  
**Session:** ACR/ARHP Poster Session C  
**Date:** Tuesday, November 18, 2014  
**Time:** 9:00 to 11:00 AM ET


**Title:** Correlation of Morning Stiffness with Measures of Higher Disease Activity in a Large U.S. Registry Population of Rheumatoid Arthritis Patients  
**Authors:** Vibeke Strand, Robert J. Holt, Katherine C. Saunders, Jeffrey D. Kent, Ping Xu, Amy Y. Grahn, Marc Mason, Carol J. Etzel  
**Location:** Room 258B  
**Abstract #:** 2813  
**Session:** ACR Concurrent Abstract Sessions (Oral)  
**Date:** Tuesday, November 18, 2014  
**Time:** 3:15 - 3:30 PM ET


In addition, the following abstract about RAYOS will be presented:

**Title:** Response of Patient Reported Symptoms of Stiffness and Pain during the Day from Adding Low-Dose Delayed-Release (DR) Prednisone to Stable DMARD Therapy over 12 Weeks in Patients with Moderate Rheumatoid Arthritis (RA)  
**Authors:** R Alten, A Grahn, P Rice, RJ Holt, F Buttgerfeit

The following abstract about VIMOVO will be presented:

**Title:** Onset, Magnitude, and Durability of Pain Relief in Patients with Knee OA Receiving a Fixed-Dose Combination Tablet of Enteric-Coated (EC) Naproxen Plus Immediate-Release (IR) Esomeprazole Magnesium Versus Celecoxib and Placebo: Pooled Results from Two Randomized Controlled Trials

**Authors:** John Fort, Robert Holt, Amy Y. Grahn, Jana Steinmetz, Ying Zhang and Jeffrey Kent

**Location:** Exhibit Hall B

**Abstract #:** 1482

**Session:** ACR/ARHP Poster Session B

**Date:** Monday, November 17, 2014

**Time:** 9:00 to 11:00 AM ET


About RAYOS®

RAYOS, known as LODOTRA® in Europe, is a proprietary delayed-release formulation of low-dose prednisone. The pharmacokinetic profile of RAYOS is different with an approximately four-hour lag time from that of immediate-release prednisone formulations. In clinical trials studying use of RAYOS in rheumatoid arthritis (RA), patients were administered RAYOS at 10 p.m. with food. The delayed-release profile of RAYOS helps to achieve therapeutic prednisone blood levels at a time point when cytokine levels start rising during the middle of the night. While the pharmacokinetic profile of RAYOS differs in terms of lag time from immediate-release prednisone, its absorption, distribution and elimination processes are comparable. For more information, please visit [www.RAYOSrx.com](http://www.RAYOSrx.com).

RAYOS utilizes Skyepharma’s proprietary Geoclock™ technology.

Outside the United States, LODOTRA is approved for the treatment of moderate to severe active RA in adults particularly when accompanied by morning stiffness in over thirty-five countries. Horizon has granted commercialization rights for LODOTRA in Europe, Asia (excluding Japan) and Latin America to its distribution partner Mundipharma International Corporation Limited. Horizon has an exclusive license from Skyepharma for RAYOS/LODOTRA.

**Approved Uses for RAYOS**

RAYOS, a delayed-release form of prednisone, prevents the release of substances in the body that cause inflammation. RAYOS is approved to treat a broad range of diseases including RA, polymyalgia rheumatica (PMR), psoriatic arthritis (PsA), ankylosing spondylitis (AS), asthma and chronic obstructive pulmonary disease (COPD). For a full list of RAYOS indications, please see full prescribing information at [www.RAYOSrx.com](http://www.RAYOSrx.com).

RAYOS is contraindicated in patients who have known hypersensitivity to prednisone or to any of the excipients. Rare instances of anaphylaxis have occurred in patients receiving corticosteroids.

**Important Safety Information about RAYOS**

Do not use RAYOS if you are allergic to prednisone. Long-term use of RAYOS can affect how your body responds to stress. Symptoms can include weight gain, severe fatigue, weak muscles and high blood sugar.

RAYOS can weaken your immune system, making it easier for you to get an infection or worsening an infection you already have or have recently had. RAYOS can cause high blood pressure, salt and water retention and low blood potassium. There is an increased risk of developing holes in the stomach or intestines if you have certain stomach and intestinal disorders. Behavior and mood changes can occur, including intense excitement or happiness, sleeplessness, mood swings, personality changes or severe depression.

Long-term use of RAYOS can cause decreases in bone density. RAYOS can cause cataracts, eye infections and glaucoma. Do not receive a "live" vaccine while taking RAYOS. The vaccine may not work as well during this time and may not fully protect you from disease. Taking RAYOS during the first trimester of pregnancy can harm an unborn baby. Long-term use of RAYOS can slow growth and development in children.
The most common side effects with RAYOS are water retention, high blood sugar, high blood pressure, unusual behavior and mood changes, increased appetite and weight gain. Please see full prescribing information for RAYOS at www.RAYOSrx.com.

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, 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 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.

Approved Uses for VIMOVO

- VIMOVO is approved to relieve the signs and symptoms of osteoarthritis, rheumatoid arthritis and ankylosing spondylitis and to decrease the risk of stomach (gastric) ulcers in patients at risk of developing stomach ulcers from treatment with NSAIDs.
- VIMOVO is not recommended as a starting treatment for relief of acute pain. Controlled studies do not extend beyond 6 months.

Important Safety Information

- **Like all medications that contain nonsteroidal anti-inflammatory drugs (NSAIDs), VIMOVO may increase the chance of a heart attack or stroke that can lead to death. This chance increases**
  - With longer use of NSAID medicines
  - In people who have heart disease
- **NSAID-containing medications, such as VIMOVO, should never be used before or after a type of heart surgery called coronary artery bypass graft (CABG).**
- **As with all medications that contain NSAIDs, VIMOVO may increase the chance of stomach and intestinal problems, such as bleeding or an ulcer, which can occur without warning and may cause death.**
  - Elderly patients are at greater risk for serious gastrointestinal events
- 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 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.

Please see accompanying full Prescribing Information for VIMOVO, including Boxed WARNINGS, with Medication Guide at www.VIMOVO.com.

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.

About CORRONA
The Consortium of Rheumatology Researchers of North America, Inc. (CORRONA) was founded in 2000 by leading rheumatologists dedicated to advancing and improving the care of patients with rheumatic and other chronic diseases. CORRONA’s mission is to advance medical research and improve the quality of patient care.

CORRONA is an independent registry without any ownership links to the pharmaceutical industry. It is run by a group of experienced academic and clinical rheumatologists throughout the country with a wide range of experience.

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