



November 12, 2012

Horizon Pharma Presents Clinical Data Demonstrating RAYOS(R) (prednisone) Delayed-Release Tablets Reduce Morning Stiffness in Patients With Active Rheumatoid Arthritis

Reduction in Morning Stiffness Correlates With ACR20, DAS28 and HAQ-DI Response

DEERFIELD, IL -- (Marketwire) -- 11/12/12 -- Horizon Pharma, Inc. (NASDAQ: HZNP) today announced an additional analysis of data from the pivotal Circadian Administration of Prednisone in Rheumatoid Arthritis-2 (CAPRA- 2) trial demonstrating that patients with active rheumatoid arthritis (RA) treated with its recently approved RAYOS® 5 mg (prednisone) delayed-release tablets who met ACR20, DAS28 and HAQ-DI response criteria had a significantly greater reduction in morning stiffness than patients who didn't meet these criteria. Data were presented during the American College of Rheumatology (ACR)/Association of Rheumatology Health Professionals (ARHP) Annual Scientific Meeting in Washington, D.C.

"Morning pain and stiffness severity, in addition to duration of morning stiffness, are key patient reported outcomes for both treatment response and disease progression in RA patients," said Dr. Frank Buttgerit, principal investigator of the study, senior consultant and deputy head of the Department of Rheumatology and Clinical Immunology, Charité Hospital, Berlin, Germany. "In addition to a reduction in morning stiffness of RA, patients treated with RAYOS also experience a significant ACR20 response and a significant reduction in DAS28 compared to immediate-release prednisone. Based on these analyses, we now better understand the strong correlation between patient response and the reduction in morning stiffness."

The efficacy of RAYOS in the treatment of RA was assessed in the CAPRA-2 trial, a double-blind, placebo-controlled, randomized, 12-week trial in patients with active rheumatoid arthritis diagnosed according to American College of Rheumatology (ACR) criteria. Enrolled patients were not currently being treated with corticosteroids and received non-biologic disease-modifying antirheumatic drug (DMARD) therapy for at least 6 months prior to receipt of study medication. Patients were randomized in a 2:1 ratio to treatment with RAYOS 5 mg (n=231) or placebo (n=119) administered at 10 p.m. in addition to their DMARD therapy. Patients ranged in age from 27 to 80 years (median age 57 years) old, were predominantly Caucasian and were predominately (84%) female.

The primary endpoint was the proportion of patients achieving ACR20 response after 12 weeks. A key secondary endpoint was the reduction of morning stiffness duration at week 12, as captured in patient daily diaries. Pearson Correlations were conducted to evaluate the relationships between change from baseline in morning stiffness duration (minutes), morning stiffness severity or pain intensity upon awakening with measures of disease DAS28 and HAQ-DI collected at patient visits. Additionally, a Wilcoxon rank sum analysis was completed between patients who responded and those that didn't respond based on ACR20, DAS28 (score < 2.6) and HAQ-DI (percent change from baseline < -0.22) and morning stiffness duration.

Results from these analyses demonstrated that morning stiffness duration, morning stiffness severity and pain intensity upon awakening correlated with DAS28 and HAQ-DI in all treatment group analyses ($p < 0.0001$). There were stronger absolute correlations seen with morning stiffness severity and pain intensity upon awakening than with morning stiffness duration, whether the treatment groups were analyzed separately or together. Specifically, a moderately strong correlation (≥ 0.5) was seen between DAS28 and morning stiffness severity and pain intensity in the treatment and placebo groups. The ranges of correlations found are similar to previous studies showing joint impairment is moderately correlated with disability (0.42-0.50) as measured by self-report questionnaires (Yazici, J Rheumatol 2004). Patients who met ACR20, DAS28 and HAQ-DI response criteria had a greater relative reduction in morning stiffness than patients who didn't meet these criteria.

There were no safety concerns for RAYOS 5 mg shown in the study beyond those already established for immediate-release prednisone.

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 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.

RAYOS utilizes SkyePharma's proprietary Geoclock™ technology.

Outside the United States, LODOTRA is approved for the treatment of moderate to severe active RA when accompanied by morning stiffness in 19 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.

Important Safety Information

RAYOS® (prednisone) delayed-release tablets

Approved uses of 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.*

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 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 Horizon Pharma

Horizon Pharma, Inc. is a biopharmaceutical company that is developing and commercializing innovative medicines to target unmet therapeutic needs in arthritis, pain and inflammatory diseases. For more information, please visit www.horizonpharma.com.

Forward-Looking Statements

This press release contains forward-looking statements, including statements regarding the potential for RAYOS to treat and improve RA symptoms such as morning stiffness and understanding of the correlation between patient response and the reduction in morning stiffness. These forward-looking statements are based on management's 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, including, but not limited to, risks regarding the company's ability to commercialize products successfully, whether physicians will prescribe and patients will use RAYOS, once available, and competition in the market for

RAYOS. For a further description of these and other risks facing Horizon, please see the risk factors described in Horizon'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 undertakes no obligation to update or revise these statements, except as may be required by law.

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Source: Horizon Pharma

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