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

DEERFIELD, IL -- (Marketwire) -- 11/11/12 -- 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) clinical trial demonstrating that patients with active rheumatoid arthritis (RA) treated with its recently approved RAYOS® 5 mg (prednisone) delayed-release tablets had a significant improvement in reduction of fatigue, as determined by the Functional Assessment of Chronic Illness Therapy - Fatigue (FACIT-F) questionnaire. Data were presented during the American College of Rheumatology (ACR)/Association of Rheumatology Health Professionals (ARHP) Annual Scientific Meeting in Washington, D.C.

"Fatigue is one of the most common symptoms of RA and it often signals the onset of joint inflammation," said Dr. Rieke Alten, chief of the Internal Medicine Division, Schlosspark Clinic, Berlin. "In the United States, approximately 50 percent of patients with severe RA are prescribed combination therapy that includes corticosteroids, with prednisone being the most common. Based on the CAPRA-2 data, RAYOS is a viable treatment option to help treat RA patients' inflammation as well as improve their symptoms, including fatigue."

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 but did receive 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 to compare treatment with RAYOS 5 mg and placebo in the change from baseline on the Functional Assessment of Chronic Illness Therapy - Fatigue (FACIT-F) questionnaire, a 13-item questionnaire that assesses the effect of fatigue on daily activity and function on a 5-point scale.

In CAPRA-2, the mean baseline FACIT-F fatigue score was comparable between patients in the RAYOS 5 mg treatment group and patients in the placebo group (29 vs. 29). The least square mean (LSM) absolute increase from baseline to Week 12 was greater in patients in the RAYOS 5 mg treatment group compared to patients in the placebo group (3.8 vs. 1.6), which indicated a reduction of fatigue. The difference in FACIT-F score between baseline and Week 12 was viewed as clinically relevant for patients in the RAYOS 5 mg treatment group, but not for patients in the placebo group (Cella et. al., 2005).

At Week 12, the LSM change from baseline was statistically significantly greater for patients in the RAYOS 5 mg treatment group than for patients in the placebo group (LSM difference=2.2 [95% CI: 0.8, 3.7], p-value=0.003). The improvement in FACIT-F score was consistent with improvement in ACR20 score.

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 U.S., 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](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 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](http://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](http://www.horizonpharma.com).

#### *Forward-Looking Statements*

This press release contains forward-looking statements, including statements regarding RAYOS's potential to serve as a viable treatment option to treat RA patients' inflammation and improve their symptoms, including fatigue. 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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