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Horizon Pharma Presents New Clinical Data Demonstrating RAYOS(R) (Prednisone) Delayed-Release Tablets Produce a Sustained Reduction in Morning Symptoms in Patients With Rheumatoid Arthritis

Data Presented During ACR/ARHP Annual Scientific Meeting

DEERFIELD, IL -- (Marketwired) -- 10/29/13 -- Horizon Pharma, Inc. (NASDAQ: HZNP) today announced new analyses of data reported for the first time from the Circadian Administration of Prednisone in Rheumatoid Arthritis-1 (CAPRA-1) clinical trial.

The data demonstrated that patients with rheumatoid arthritis (RA) treated with Horizon's approved RAYOS[®] (prednisone) delayed-release (DR) tablets, given at bedtime, had significant and sustained improvement in morning symptoms for the one-year duration of the study as compared to a group of patients treated with immediate release (IR) prednisone, given in the waking hours. The data also showed that patients previously treated for three months with IR prednisone who were switched to RAYOS experienced significant improvement in morning symptoms and an associated inflammatory marker for the nine-month treatment period. The data were presented during the American College of Rheumatology (ACR)/Association of Rheumatology Health Professionals (ARHP) Annual Scientific Meeting, taking place in San Diego, CA, October 25-30, 2013.

"It is well known that morning symptoms of rheumatoid arthritis, including joint stiffness and pain, are extremely common and are associated with inflammatory circadian rhythms and the night time rise of cytokines in the body. These new analyses further indicate that the timing of prednisone administration is important to improve morning symptoms and associated inflammation in patients with rheumatoid arthritis," commented Allan Gibofsky, M.D., senior author of one of the two abstracts presented at the ACR meeting, and Professor of Medicine and Public Health at Weill Cornell Medical College and Attending Rheumatologist at the Hospital for Special Surgery in New York City.

The CAPRA-1 trial was conducted in two phases. The first phase was a double-blind, three-month active comparator controlled study that randomized RA patients on a stable low dose of prednisone therapy to either RAYOS (N=144) taken once daily at bedtime (approximately 10 p.m.) or to continue on IR prednisone (N=144), taken in the morning. Both groups received the equivalent prednisone dose previously administered. Visits included baseline, weeks 2, 6 and 12. The second phase was open-label treatment, which allowed those patients previously randomized to IR prednisone who completed the first phase of the study (N=129) to switch to RAYOS. Those patients previously randomized to RAYOS who completed the first phase of the study (N=120) were permitted to continue on RAYOS. Visits included baseline (switch at end of double-blind phase), 3, 6, and 9 months. Inflammatory cytokine interleukin (IL)-6 samples were obtained at baseline and 9 months. The primary outcomes for these analyses were absolute and relative reduction in morning stiffness, threshold responses of at least 25%, 50%, and 75% improvement in morning stiffness duration from baseline, change in mean absolute pain measured in a visual analog scale (VAS), change in mean absolute patient global assessment VAS, and IL-6 levels. For both analyses, patients who entered the open-label phase were required to have at least one diary entry. All diary entries \pm 4 weeks of each of the 3 month visits were utilized. No additional safety signals were identified in analyses conducted for either abstract presentation.

- According to the presentation titled, ***Threshold Analysis of Patient Reported Morning Stiffness Where Delayed-Release (DR) Prednisone Was Compared to, and Replaced, Immediate Release Prednisone in Rheumatoid Arthritis (RA) Patients Receiving Conventional Disease-Modifying Antirheumatic Drugs (DMARDs) Over 1 Year***, the RAYOS study arm had statistically significantly more responders in each of the 3 response categories (25/50/75%) of morning stiffness at the end of the double-blind period as compared to IR prednisone ($p \leq 0.05$), and the separation of responses began after the first week of therapy. Patients who were randomized to IR prednisone in the blinded phase, when switched to RAYOS in the open-label phase, had comparable responses in all categories within three months and significantly shorter time to response when compared to patients already receiving RAYOS ($p \leq 0.008$). The data abstract is available at: <https://ww2.rheumatology.org/apps/MyAnnualMeeting/Abstract/32990>.
- In the presentation titled, ***Switching From Immediate Release (IR) Prednisone to Delayed Release (DR) Prednisone Improves Patient Reported Outcomes In Rheumatoid Arthritis (RA) Patients On Conventional Disease-Modifying Antirheumatic Drugs (DMARDs)***, the absolute reduction of morning stiffness duration was approximately 50 minutes from baseline (end double-blind phase) for patients switching from IR prednisone to RAYOS at the initiation of the open-label phase. The relative reduction in morning stiffness duration was observed at the first visit after switching treatment regimens and was maintained over the nine months of open-label treatment. A significant improvement in pain VAS (mean absolute change -6.1, $p = 0.002$) three months after the switch from IR prednisone to RAYOS was observed and then a stabilization with a non-significant reduction at month 9. A significant improvement in patients' global assessment VAS (mean absolute change -7.9, $p < 0.0001$) was observed at month 3 and month 6 (-6.6, $p = 0.008$) after the switch

from IR prednisone to RAYOS, then a non-significant reduction at month 9. IL-6 levels were reduced in patients that switched to RAYOS by 53% from baseline ($p < 0.001$). The data abstract is available at:

<https://ww2.rheumatology.org/apps/MyAnnualMeeting/Abstract/34567>.

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 IR 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 inflammatory cytokine levels start rising during the middle of the night. While the pharmacokinetic profile of RAYOS differs in terms of lag time from IR prednisone, its absorption, distribution and elimination processes are comparable. For more information, please visit 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 when accompanied by morning stiffness in over 30 countries. Horizon has granted commercialization rights for LODOTRA in Europe, Asia 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 rheumatoid arthritis (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 specialty pharmaceutical company that has developed and is commercializing DUEXIS[®] and RAYOS/LODOTRA, both of which target unmet therapeutic needs in arthritis, pain and inflammatory diseases. The Company's strategy is to develop, acquire, in-license and/or co-promote additional innovative medicines where it can execute a targeted commercial approach in specific therapeutic areas while taking advantage of its commercial strengths and the infrastructure the Company has put in place. 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 produce a sustained reduction in morning symptoms in patients with RA and to improve outcomes in RA patients switching from IR prednisone and the importance of timing of prednisone administration in improving morning symptoms and associated inflammation in patients with RA. 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, how physicians prescribe and patients use RAYOS, 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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