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Horizon Pharma Begins Initial Commercial Launch of RAYOS(R) (prednisone) Delayed-Release Tablets in the United States

DEERFIELD, IL -- (Marketwire) -- 12/03/12 -- Horizon Pharma, Inc. (NASDAQ: HZNP) today announced that RAYOS® (prednisone) delayed release tablets are now available to U.S. physicians 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). The focus of the commercial launch will be in rheumatologic diseases, such as RA and PMR. The Company will initially target approximately one thousand rheumatologists in the U.S. with thirteen rheumatology sales specialists. The full launch to the majority of U.S. rheumatologists and high-value primary care physicians with Horizon's entire sales force of approximately one hundred fifty representatives will begin in late January 2013.

"The commercial launch of RAYOS further affirms our commitment to provide innovative therapeutic options to patients who suffer from arthritis, pain and inflammatory diseases and to the physicians who treat them," said Todd Smith, executive vice president and chief commercial officer, Horizon Pharma. "Our near term focus is on top-tier rheumatologists to prepare the market for the full rheumatology and primary care launch in late January 2013."

In July of this year, the U.S. Food and Drug Administration (FDA) approved Horizon's new drug application (NDA) for RAYOS. The FDA approval was supported by data bridging the pharmacokinetics of RAYOS to immediate-release prednisone and data from the Circadian Administration of Prednisone in RA (CAPRA-1 and 2) trials. The CAPRA-2 trial demonstrated that people with moderate to severe RA treated with RAYOS experienced a statistically significant improvement in ACR20 response criteria compared to placebo in addition to their non-biologic disease-modifying antirheumatic drug (DMARD) therapy. The CAPRA-1 trial supported the overall safety of RAYOS.

Specific results from CAPRA-2 demonstrated:

- A statistically significant improvement in ACR20 response criteria, the primary study endpoint, for patients who were treated with RAYOS compared to the placebo group (47% vs. 29%; p-value = 0.001).
- A statistically significant improvement in ACR50 response compared to placebo (22% vs. 10%; p-value = 0.007) and an improvement in the more stringent ACR70 response criteria (7% vs. 3%; p-value = 0.0984). Both ACR50 and ACR70 were pre-specified secondary endpoints.
- The relative change from baseline in the duration of morning stiffness at 12 weeks was assessed as a pre-specified secondary endpoint. Patients treated with RAYOS had a median decrease in the duration of morning stiffness of 55 minutes compared to 33 minutes in placebo-treated patients (20 minute estimated median difference between treatment groups with 95% confidence interval [7, 32; p-value = 0.001]).

Results from CAPRA-2 were published online in *Annals of the Rheumatic Diseases* (doi:10.1136/annrheumdis-2011-201067) on May 5, 2012.

The safety of RAYOS was based on the evaluation of 375 RA patients in two controlled trials. Patients treated with RAYOS ranged in age from 20 to 80 years (median age 56 years). Patients were predominantly Caucasian and 85 percent were female.

Included in these safety results were data from the CAPRA-1 trial, a 12-week, double-blind, randomized controlled study that evaluated 288 RA patients. CAPRA-1 compared 10 p.m. administration of RAYOS with the morning administration of immediate-release prednisone at the same individual dose (average dose of 6.7 mg). Following the 12-week CAPRA-1 study, patients were followed in a 9-month, open-label extension study, which included 249 RA patients, 219 of whom completed the extension study. Patients received RAYOS 3 mg to 10 mg once daily at 10 p.m.; the majority (84 percent) received 5 mg or less.

The clinical trial experience did not raise any safety concerns beyond those already established for immediate-release prednisone.

Results from the CAPRA-1 12-week study and the 9-month open-label extension have been published in *The Lancet* and *Annals of the Rheumatic Diseases*, respectively.

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

RAYOS utilizes SkyePharma's proprietary Geoclock™ technology under an exclusive license from SkyePharma.

Outside the U.S., LODOTRA is approved in 19 countries for the treatment of moderate to severe active RA when accompanied by morning stiffness. Horizon has granted commercialization rights for LODOTRA in Europe, Asia (excluding Japan) and Latin America to its distribution partner Mundipharma International Corporation Limited.

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 Horizon's commercialization plans for RAYOS and the timing for implementing those plans. 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, potential delays or changes in strategy for the commercial launch of RAYOS, whether physicians will prescribe and patients will 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. Horizon undertakes no obligation to update or revise these statements, except as may be required by law.

Contacts:

Todd N. Smith

Executive Vice President, Chief Commercial Officer

Email Contact

Kathy Galante

Burns McClellan, Inc.

212-213-0006

Email Contact

Source: Horizon Pharma

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