Horizon Therapeutics plc Submits Regulatory Filing for UPLIZNA® (inebilizumab) in Brazil

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DUBLIN--(BUSINESS WIRE)--Jun. 15, 2022-- Horizon Therapeutics plc (Nasdaq: HZNP) today announced that it has submitted a regulatory filing to the Brazil National Health Surveillance Agency (ANVISA) for UPLIZNA for the treatment of adult patients with anti-aquaporin-4 immunoglobulin G seropositive (AQP4-IgG+) neuromyelitis optica spectrum disorder (NMOSD).

“This regulatory submission is an important milestone as we continue to expand our commitment to NMOSD patients around the world,” said Vikram Karnani, executive vice president and president, international operations, Horizon. “NMOSD is a devastating disease with unpredictable attacks, which can result in potential loss of vision and motor function. We are hopeful that we can bring a potential new treatment option to the estimated ten thousand people living with NMOSD in Brazil.”

In the N-MOmentum Phase 3 clinical trial, the largest NMOSD trial to date, UPLIZNA demonstrated a significant reduction in the risk of an NMOSD attack with only two infusions per year, following the initial two loading doses. Additionally, 89% of patients in the AQP4-IgG+ group remained attack-free during the six-month period post-treatment and 83% of patients on treatment remained attack-free for at least four years.[1,2]

UPLIZNA was approved by the U.S. Food and Drug Administration (FDA) in June 2020, by the Japanese Ministry of Health, Labor and Welfare in March 2021 and by the European Commission (EC) in April 2022. Mitsubishi Tanabe Pharma Corporation has the rights to develop and commercialize UPLIZNA in Japan, Thailand, South Korea, Indonesia, Vietnam, Malaysia, the Philippines, Singapore and Taiwan. Hansoh Pharmaceutical Group Company Limited, another strategic partner to Horizon, has also recently received manufacturing and marketing approval from the National Medical Products Administration of the People’s Republic of China for UPLIZNA.

About Neuromyelitis Optica Spectrum Disorder (NMOSD)

NMOSD is a unifying term for neuromyelitis optica (NMO) and related syndromes. NMOSD is a rare, severe, relapsing, neuroinflammatory autoimmune disease that attacks the optic nerve, spinal cord, brain and brain stem.[3-4] Approximately 80% of all patients with NMOSD test positive for anti-AQP4 antibodies.[5] AQP4-IgG binds primarily to astrocytes in the central nervous system and triggers an escalating immune response that results in lesion formation and astrocyte death.[6]

Anti-AQP4 autoantibodies are produced by plasmablasts and plasma cells. These B-cell populations are central to NMOSD disease pathogenesis, and a large proportion of these cells express CD19.[7] Depletion of these CD19 B cells is thought to remove an important contributor to inflammation, lesion formation and astrocyte damage. Clinically, this damage presents as an NMOSD attack, which can involve the optic nerve, spinal cord and brain.[6-8] Loss of vision, paralysis, loss of sensation, bladder and bowel dysfunction, nerve pain and respiratory failure can all be manifestations of the disease.[9] Each NMOSD attack can lead to further cumulative damage and disability.[10,11] NMOSD occurs more commonly in women and may be more common in individuals of African and Asian descent.[12,13]

About UPLIZNA (inebilizumab-cdon)

INDICATION

UPLIZNA is indicated for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive.

IMPORTANT SAFETY INFORMATION

UPLIZNA is contraindicated in patients with:

- A history of life-threatening infusion reaction to UPLIZNA
- Active hepatitis B infection
- Active or untreated latent tuberculosis

WARNINGS AND PRECAUTIONS

Infusion Reactions: UPLIZNA can cause infusion reactions, which can include headache, nausea, somnolence, dyspnea, fever, myalgia, rash or other symptoms. Infusion reactions were most common with the first infusion but were also observed during subsequent infusions. Administer pre-medication with a corticosteroid, an antihistamine and an anti-pyretic.

Infections: The most common infections reported by UPLIZNA-treated patients in the randomized and open-label periods included urinary tract infection (20%), nasopharyngitis (13%), upper respiratory tract infection (8%) and influenza (7%). Delay UPLIZNA administration in patients with an active infection until the infection is resolved.

Increased immunosuppressive effects are possible if combining UPLIZNA with another immunosuppressive therapy.

The risk of Hepatitis B Virus (HBV) reactivation has been observed with other B-cell-depleting antibodies. Perform HBV screening in all patients before initiation of treatment with UPLIZNA. Do not administer to patients with active hepatitis.

Although no confirmed cases of Progressive Multifocal Leukoencephalopathy (PML) were identified in UPLIZNA clinical trials, JC virus infection resulting in PML has been observed in patients treated with other B-cell-depleting antibodies and other therapies that affect immune competence. At the first sign or symptom suggestive of PML, withhold UPLIZNA and perform an appropriate diagnostic evaluation.

Patients should be evaluated for tuberculosis risk factors and tested for latent infection prior to initiating UPLIZNA.

Vaccination with live-attenuated or live vaccines is not recommended during treatment and after discontinuation, until B-cell repletion.

Reduction in Immunoglobulins: There may be a progressive and prolonged hypogammaglobulinemia or decline in the levels of total and individual immunoglobulins such as immunoglobulins G and M (IgG and IgM) with continued UPLIZNA treatment. Monitor the level of immunoglobulins at the beginning, during, and after discontinuation of treatment with UPLIZNA until B-cell repletion especially in patients with opportunistic or recurrent infections.

Fetal Risk: May cause fetal harm based on animal data. Advise females of reproductive potential of the potential risk to a fetus and to use an effective method of contraception during treatment and for 6 months after stopping UPLIZNA.

Adverse Reactions: The most common adverse reactions (at least 10% of patients treated with UPLIZNA and greater than placebo) were urinary tract infection and arthralgia.

For additional information on UPLIZNA, please see the Full Prescribing Information at www.UPLIZNA.com.

About Horizon

Horizon is a global biotechnology company focused on the discovery, development and commercialization of medicines that address critical needs for people impacted by rare, autoimmune and severe inflammatory diseases. Our pipeline is purposeful: We apply scientific expertise and courage to bring clinically meaningful therapies to patients. We believe science and compassion must work together to transform lives. For more information on how we go to incredible lengths to impact lives, visit www.horizontherapeutics.com and follow us on Twitter, LinkedIn, Instagram and Facebook.

Forward-Looking Statements

This press release contains forward-looking statements, including, but not limited to, statements related to potential regulatory approval of UPLIZNA in Brazil and the potential benefits of UPLIZNA to patients in Brazil. These forward-looking statements are based on management 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. These factors include the risk that UPLIZNA does not receive regulatory approval in Brazil, whether, if regulatory approval is received, UPLIZNA will be successfully commercialized in Brazil, and those risks detailed from time-to-time under the caption "Risk Factors" and elsewhere in Horizon's filings and reports with the SEC. Horizon undertakes no duty or obligation to update any forward-looking statements contained in this press release as a result of new information.

References

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