



New UPLIZNA® (inebilizumab-cdon) Data in People With Neuromyelitis Optica Spectrum Disorder (NMOSD) to be Presented at the American Academy of Neurology’s 73rd Annual Meeting

April 5, 2021

-- Data from the pivotal N-MOMentum trial will highlight UPLIZNA long-term safety and efficacy, as well as its impact on pain in NMOSD patients --

-- New survey results demonstrate NMOSD patient attitudes towards diagnosis and treatment --

DUBLIN--(BUSINESS WIRE)--Apr. 5, 2021-- Horizon Therapeutics plc (Nasdaq: HZNP) today announced new UPLIZNA (inebilizumab-cdon) data will be presented at the American Academy of Neurology’s 73rd Annual Meeting, which will be held virtually April 17-22, 2021. UPLIZNA is the first and only FDA-approved B-cell depleter for the treatment of adult patients with anti-aquaporin-4 (AQP4) antibody positive NMOSD.

UPLIZNA data being presented at AAN 2021 include:

- **Inebilizumab Treatment Reduces the Occurrence of Pain in NMOSD Patients**
 - **Session:** [P2.017](#), H. Kim
 - **Date:** On Demand (scientific poster)
- **Long-Term Efficacy Outcomes with Inebilizumab Treatment in NMOSD: the N-MOMentum Trial**
 - **Session:** [P15.076](#), B. Cree
 - **Date:** On Demand (scientific poster)
- **Long-Term Safety Outcomes with Inebilizumab Treatment in NMOSD: the N-MOMentum Trial**
 - **Session:** [P15.100](#), B. Cree
 - **Date:** On Demand (scientific poster)
- **Evaluation of Infusion Reactions and Infusion Times in the N-MOMentum Study of Inebilizumab for NMOSD**
 - **Session:** [P15.211](#), M. Tullman
 - **Date:** On Demand (scientific poster)
- **Pharmacodynamic Modeling and Exposure-Response Assessment of Inebilizumab in Subjects With Neuromyelitis Optica Spectrum Disorder**
 - **Session:** [S29.003](#), L. Yan
 - **Date:** Wednesday, April 21, 2021, 4:24 p.m. ET (live broadcast)

Additional data highlighting NMOSD patient perspectives being presented at AAN 2021 include:

- **Patient Attitudes Towards NMOSD Diagnosis and Treatment: Final Survey Results**
 - **Session:** [P2.106](#), G. Garcia
 - **Date:** On Demand (scientific poster)

In addition, Horizon will host two Industry Therapeutic Updates. The first is on Tuesday, April 20, 2021 at 1 p.m. ET called “Advances in NMOSD Treatment: Inebilizumab-cdon,” featuring Adil Javed, M.D. Ph.D., associate professor of neurology, University of Chicago. The second is on Wednesday, April 21, 2021 at 9 a.m. ET called “B Cell Biology in Myasthenia Gravis: From Pathogenesis to Targeted Therapies.”

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 and brain stem.^{1,2} Approximately 80% of all patients with NMOSD test positive for anti-AQP4 antibodies.³ These AQP4 autoantibodies are produced by CD19+ B cells and bind primarily to astrocytes in the central nervous system.⁴ Binding of AQP4 antibodies to central and peripheral nervous system cells is believed to trigger attacks, which can damage the optic nerve, spinal cord and brain.^{4,5} Loss of vision, paralysis, loss of sensation, bladder and bowel dysfunction, nerve pain and respiratory failure can all be manifestations of the disease.⁶ Each NMOSD attack can lead to further damage and disability.^{2,7,8} NMOSD occurs more commonly in women and may be more common in individuals of African and Asian descent.^{9,10}

About UPLIZNA

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 Prescribing Information at www.UPLIZNA.com.

About Horizon

Horizon is 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, please visit www.horizontherapeutics.com and follow us on [Twitter](#), [LinkedIn](#), [Instagram](#) and [Facebook](#).

References

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Tina Ventura

Senior Vice President, Investor Relations

Investor-relations@horizontherapeutics.com

Ruth Venning

Executive Director, Investor Relations

Investor-relations@horizontherapeutics.com

U.S. Media Contacts:

Rachel Vann

Director, Product Communications

media@horizontherapeutics.com

Ireland Media Contact:

Gordon MRM

Ray Gordon

ray@gordonmrm.ie

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