Alexion data at AAN 2024 demonstrate how ULTOMIRIS® and SOLIRIS® can transform outcomes for rare neurological diseases

April 8, 2024

Alexion data at AAN 2024 demonstrate how ULTOMIRIS® and SOLIRIS® can transform outcomes for rare neurological diseases

New findings from CHAMPION-NMOSD trial will reinforce the potential for ULTOMIRIS to eliminate relapses and improve care in AQP4 Ab+ NMOSD

Long-term data and real-world evidence in gMG will underscore vital role of ULTOMIRIS and SOLIRIS in treatment landscape and show sustained patient benefit

Alexion, AstraZeneca Rare Disease, will present new clinical and real-world data from its leading rare neurology portfolio at the American Academy of Neurology (AAN) Annual Meeting in Denver, CO, April 13 to 18, 2024. The company will present 14 abstracts, including five oral presentations, across both generalized myasthenia gravis (gMG) and neuromyelitis optica spectrum disorder (NMOSD).

Presentations include new long-term results from the pivotal Phase III CHAMPION-MG and CHAMPION-NMOSD trials, as well as real-world data, adding to the robust evidence supporting the safety and efficacy of ULTOMIRIS® (ravulizumab-cwvz) and SOLIRIS® (eculizumab) in gMG and NMOSD.

Christophe Hotermans, Senior Vice President, Head of Global Medical Affairs, Alexion, said: “ULTOMIRIS and SOLIRIS bring innovation and hope to the gMG and NMOSD communities, offering treatment options with the potential to transform care for these debilitating diseases. Our data at AAN will showcase outcomes in both clinical and real-world settings that clearly demonstrate the sustained benefit of ULTOMIRIS and SOLIRIS in these patient populations. We remain committed to advancing care and innovative solutions for people living with these rare neurological conditions.”

Continued evidence supporting long-term efficacy and safety of ULTOMIRIS in NMOSD and gMG

Two oral presentations will detail new findings on the long-term safety and efficacy of ULTOMIRIS in adults with the most common forms of NMOSD and gMG.

Long-term results from the ongoing global, open-label CHAMPION-NMOSD trial will demonstrate the potential for ULTOMIRIS to eliminate relapses in people living with anti-aquaporin-4 (AQP4) antibody-positive (Ab+) NMOSD. Data will show there were zero adjudicated on-trial relapses observed in ULTOMIRIS-treated patients with AQP4 Ab+ NMOSD, with a median treatment duration of 138 weeks.

Further, the final analysis from the global CHAMPION-MG open-label extension will underscore the benefits of sustained treatment of ULTOMIRIS in patients with anti-acetylcholine receptor (AChR) Ab+ gMG. Improvements in measures of functional activities and quality of life, including Myasthenia Gravis-Activities of
Daily Living (MG-ADL) and Quantitative Myasthenia Gravis (QMG) total scores, were maintained in ULTOMIRIS-treated patients for up to 164 weeks.

**Real-world data highlight benefit of C5 inhibitors in gMG clinical practice**

An oral presentation will report results from a retrospective US-based medical record analysis, which suggests earlier treatment initiation with C5 inhibitor therapy offers greater clinical benefit for patients with gMG. While MG-ADL scores improved for patients who initiated SOLIRIS early or late, greater improvements were observed among those who started treatment within two years of their gMG diagnosis.

Two poster presentations will discuss steroid usage patterns and outcomes when used to treat chronic gMG, including after treatment with C5 inhibitors. A retrospective observational cohort study evaluating Medicare claims will indicate high rates of comorbidities among patients with gMG, which may inform clinical practice when prescribing corticosteroids. Additional medical claims data will show statistically significant reductions in the daily use of corticosteroids after 12 months of treatment with C5 inhibitors, as well as reductions in gMG exacerbations, supporting the use of C5 inhibitors as steroid-sparing therapy.

Findings from a gMG global registry will also be shared, including an encore oral presentation that will show patients who have been treated with SOLIRIS in clinical practice experience decreased rates of myasthenic crisis, exacerbations and hospitalizations.

**Uncovering new insights in NMOSD therapeutic efficacy**

An oral presentation will highlight results from a study evaluating specific biomarkers as measures of biological response to treatment with ULTOMIRIS and SOLIRIS from the global Phase III PREVENT and CHAMPION-NMOSD trials. The data will show glial fibrillary acidic protein (GFAP) and neurofilament light chain (NFL) levels, biomarkers for astrocyte and neuronal injury, decreased over time with C5 inhibitor treatment and may be additional indicators of therapeutic efficacy when evaluating treatments for AQP4 Ab+ NMOSD.

**Alexion presentations during AAN 2024**

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*Ad Scientiam research study supported by Alexion

**INDICATION(S) & IMPORTANT SAFETY INFORMATION FOR ULTOMIRIS® (ravulizumab-cwvz)**

**INDICATION(S)**

What is ULTOMIRIS?
ULTOMIRIS is a prescription medicine used to treat:

- adults and children 1 month of age and older with a disease called Paroxysmal Nocturnal Hemoglobinuria (PNH).
- adults and children 1 month of age and older with a disease called atypical Hemolytic Uremic Syndrome (aHUS). ULTOMIRIS is not used in treating people with Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS).
- adults with a disease called generalized Myasthenia Gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody positive.
- adults with a disease called Neuromyelitis Optica Spectrum Disorder (NMOSD) who are anti-aquaporin 4 (AQP4) antibody positive.

It is not known if ULTOMIRIS is safe and effective in children younger than 1 month of age.

It is not known if ULTOMIRIS is safe and effective for the treatment of gMG or NMOSD in children.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about ULTOMIRIS?

ULTOMIRIS is a medicine that affects your immune system and may lower the ability of your immune system to fight infections.

- ULTOMIRIS increases your chance of getting serious meningococcal infections that may quickly become life-threatening or cause death if not recognized and treated early.

1. You must complete or update meningococcal vaccine(s) at least 2 weeks before your first dose of ULTOMIRIS.
2. If you have not completed your meningococcal vaccines and ULTOMIRIS must be started right away, you should receive the required vaccine(s) as soon as possible.
3. If you have not been vaccinated and ULTOMIRIS must be started right away, you should also receive antibiotics for as long as your healthcare provider tells you.
4. If you had a meningococcal vaccine in the past, you might need additional vaccines before starting ULTOMIRIS. Your healthcare provider will decide if you need additional meningococcal vaccines.
5. Meningococcal vaccines do not prevent all meningococcal infections. Call your healthcare provider or get emergency medical care right away if you get any of these signs and symptoms of a meningococcal infection: fever, fever with high heart rate, headache and fever, confusion, muscle aches with flu-like symptoms, fever and a rash, headache with nausea or vomiting, headache with a stiff neck or stiff back, or eyes sensitive to light.

Your healthcare provider will give you a Patient Safety Card about the risk of serious meningococcal infection. Carry it with you at all times during treatment and for 8 months after your last ULTOMIRIS dose. Your risk of meningococcal infection may continue for several months after your last dose of ULTOMIRIS. It is important to show this card to any healthcare provider who treats you. This will help them diagnose and treat you quickly.

ULTOMIRIS is only available through a program called the ULTOMIRIS and SOLIRIS Risk Evaluation and Mitigation Strategy (REMS). Before you can receive ULTOMIRIS, your healthcare provider must: enroll in the REMS program; counsel you about the risk of serious meningococcal infections; give you information about the signs and symptoms of serious meningococcal infection; make sure that you are vaccinated against serious infections caused by meningococcal bacteria, and that you receive antibiotics if you need to start ULTOMIRIS right away and are not up to date on your vaccines; give you a Patient Safety Card about
ULTOMIRIS may also increase the risk of other types of serious infections, including Streptococcus pneumoniae, Haemophilus influenzae, and Neisseria gonorrhoeae. Your child should receive vaccines against Streptococcus pneumoniae and Haemophilus influenzae type b (Hib) if treated with ULTOMIRIS. Certain people may be at risk of serious infections with gonorrhea.

Who should not receive ULTOMIRIS?

Do not receive ULTOMIRIS if you have a serious meningococcal infection when you are starting ULTOMIRIS.

Before you receive ULTOMIRIS, tell your healthcare provider about all of your medical conditions, including if you: have an infection or fever, are pregnant or plan to become pregnant, and are breastfeeding or plan to breastfeed. It is not known if ULTOMIRIS will harm your unborn baby or if it passes into your breast milk. You should not breastfeed during treatment and for 8 months after your final dose of ULTOMIRIS.

Tell your healthcare provider about all the vaccines you receive and medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements which could affect your treatment.

If you have PNH and you stop receiving ULTOMIRIS, your healthcare provider will need to monitor you closely for at least 16 weeks after you stop ULTOMIRIS. Stopping ULTOMIRIS may cause breakdown of your red blood cells due to PNH. Symptoms or problems that can happen due to red blood cell breakdown include: drop in your red blood cell count, tiredness, blood in your urine, stomach-area (abdomen) pain, shortness of breath, blood clots, trouble swallowing, and erectile dysfunction (ED) in males.

If you have aHUS, your healthcare provider will need to monitor you closely for at least 12 months after stopping treatment for signs of worsening aHUS or problems related to a type of abnormal clotting and breakdown of your red blood cells called thrombotic microangiopathy (TMA). Symptoms or problems that can happen with TMA may include: confusion or loss of consciousness, seizures, chest pain (angina), difficulty breathing and blood clots or stroke.

What are the possible side effects of ULTOMIRIS?

ULTOMIRIS can cause serious side effects including infusion-related reactions. Symptoms of an infusion-related reaction with ULTOMIRIS may include lower back pain, abdominal pain, muscle spasms, changes in blood pressure, tiredness, feeling faint, shaking chills (rigors), discomfort in your arms or legs, bad taste, or drowsiness. Stop treatment of ULTOMIRIS and tell your healthcare provider right away if you develop these symptoms, or any other symptoms during your ULTOMIRIS infusion that may mean you are having a serious infusion-related reaction, including: chest pain, trouble breathing or shortness of breath, swelling of your face, tongue, or throat, and feel faint or pass out.

The most common side effects of ULTOMIRIS in people treated for PNH are upper respiratory tract infection and headache.

The most common side effects of ULTOMIRIS in people treated for aHUS are upper respiratory tract infection, diarrhea, nausea, vomiting, headache, high blood pressure and fever.

The most common side effects of ULTOMIRIS in people with gMG are diarrhea and upper respiratory tract infections.
The most common side effects of ULTOMIRIS in people with NMOSD are COVID-19 infection, headache, back pain, urinary tract infection, and joint pain (arthralgia).

Tell your healthcare provider about any side effect that bothers you or that does not go away. These are not all the possible side effects of ULTOMIRIS. For more information, ask your healthcare provider or pharmacist. Call your healthcare provider right away if you miss an ULTOMIRIS infusion or for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Please see the accompanying full Prescribing Information and Medication Guide for ULTOMIRIS, including Boxed WARNING regarding serious meningococcal infections.

INDICATION(S) & IMPORTANT SAFETY INFORMATION FOR SOLIRIS® (eculizumab)

INDICATION(S)

What is SOLIRIS?

SOLIRIS is a prescription medicine used to treat:

- people with paroxysmal nocturnal hemoglobinuria (PNH).
- people with atypical hemolytic uremic syndrome (aHUS). SOLIRIS is not for use in treating people with Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS).
- adults with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody positive.
- adults with a disease called neuromyelitis optica spectrum disorder (NMOSD) who are anti-aquaporin-4 (AQP4) antibody positive.

It is not known if SOLIRIS is safe and effective in children with PNH, gMG, or NMOSD.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about SOLIRIS?

SOLIRIS is a medicine that affects your immune system and may lower the ability of your immune system to fight infections.

- SOLIRIS increases your chance of getting serious meningococcal infections that may quickly become life-threatening or cause death if not recognized and treated early.

  1. You must complete or update your meningococcal vaccine(s) at least 2 weeks before your first dose of SOLIRIS.
  2. If you have not been vaccinated and SOLIRIS must be started right away, you should receive the required vaccine(s) as soon as possible.
  3. If you have not been vaccinated and SOLIRIS must be started right away, you should also receive antibiotics for as long as your healthcare provider tells you.
  4. If you had a meningococcal vaccine in the past, you might need additional vaccines before starting SOLIRIS. Your healthcare provider will decide if you need additional meningococcal vaccines.
  5. Meningococcal vaccines do not prevent all meningococcal infections. Call your healthcare provider or get emergency medical care right away if you get any of these signs and symptoms of a serious meningococcal infection: fever, fever with high heart rate, headache and fever, confusion, muscle aches with flu-like symptoms, fever and rash, headache with nausea or vomiting, headache with a stiff neck or stiff back, or eyes sensitive to light.

Your healthcare provider will give you a Patient Safety Card about the risk of serious meningococcal
Your risk of meningococcal infection may continue for several weeks after your last dose of SOLIRIS. It is important to show this card to any healthcare provider who treats you. This will help them diagnose and treat you quickly.

SOLIRIS is only available through a program called the ULTOMIRIS and SOLIRIS Risk Evaluation and Mitigation Strategy (REMS). Before you can receive SOLIRIS, your healthcare provider must: enroll in the REMS program; counsel you about the risk of serious meningococcal infections; give you information about the signs and symptoms of serious meningococcal infection; make sure that you are vaccinated against serious infections caused by meningococcal bacteria, and that you receive antibiotics if you need to start SOLIRIS right away and you are not up to date on your vaccines; give you a Patient Safety Card about your risk of meningococcal infection.

SOLIRIS may also increase the risk of other types of serious infections, including *Streptococcus pneumoniae*, *Haemophilus influenzae*, and *Neisseria gonorrhoeae*. Your child should receive vaccines against *Streptococcus pneumoniae* and *Haemophilus influenzae* type b (Hib) if treated with SOLIRIS. Certain people may be at risk of serious infections with gonorrhea. Certain fungal infections (*Aspergillus*) may occur if you take SOLIRIS and have a weak immune system or a low white blood cell count.

**Who should not receive SOLIRIS?**

Do not receive SOLIRIS if you have a serious meningococcal infection when you are starting SOLIRIS.

**Before you receive SOLIRIS, tell your healthcare provider about all of your medical conditions, including if you:** have an infection or fever, are pregnant or plan to become pregnant, and are breastfeeding or plan to breastfeed. It is not known if SOLIRIS will harm your unborn baby or if it passes into your breast milk.

Tell your healthcare provider about all the vaccines you receive and medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements which could affect your treatment.

If you have PNH, your healthcare provider will need to monitor you closely for at least 8 weeks after stopping SOLIRIS. Stopping treatment with SOLIRIS may cause breakdown of your red blood cells due to PNH. Symptoms or problems that can happen due to red blood cell breakdown include: drop in the number of your red blood cell count, drop in your platelet count, confusion, kidney problems, blood clots, difficulty breathing, and chest pain.

If you have aHUS, your healthcare provider will need to monitor you closely during and for at least 12 weeks after stopping SOLIRIS for signs of worsening aHUS symptoms or problems related to abnormal clotting (thrombotic microangiopathy). Symptoms or problems that can happen with abnormal clotting may include: stroke, confusion, seizure, chest pain (angina), difficulty breathing, kidney problems, swelling in arms or legs, and a drop in your platelet count.

**What are the possible side effects of SOLIRIS?**

SOLIRIS can cause serious side effects including serious infusion-related reactions. Tell your healthcare provider or nurse right away if you get any of these symptoms during your SOLIRIS infusion: chest pain, trouble breathing or shortness of breath, swelling of your face, tongue, or throat, and feel faint or pass out. If you have an infusion-related reaction to SOLIRIS, your healthcare provider may need to infuse SOLIRIS more slowly, or stop SOLIRIS.

The most common side effects in people with aHUS treated with SOLIRIS include: headache,
diarrhea, high blood pressure (hypertension), common cold (upper respiratory infection), stomach-area (abdominal) pain, vomiting, pain or swelling of your nose or throat (nasopharyngitis), low red blood cell count (anemia), cough, swelling of legs or feet (peripheral edema), nausea, urinary tract infections, and fever.

**The most common side effects in people with gMG treated with SOLIRIS include:** muscle and joint (musculoskeletal) pain.

**The most common side effects in people with NMOSD treated with SOLIRIS include:** common cold (upper respiratory infection), pain or swelling of your nose or throat (nasopharyngitis), diarrhea, back pain, dizziness, flu like symptoms (influenza) including fever, headache, tiredness, cough, sore throat, and body aches, joint pain (arthralgia), throat irritation (pharyngitis), and bruising (contusion).

Tell your healthcare provider about any side effect that bothers you or that does not go away. These are not all the possible side effects of SOLIRIS. For more information, ask your healthcare provider or pharmacist. Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Please see the accompanying full Prescribing Information and Medication Guide for SOLIRIS, including Boxed WARNING regarding serious meningococcal infections.

**Notes**

**ULTOMIRIS® (ravulizumab-cwvz)**

ULTOMIRIS® (ravulizumab-cwvz), the first and only long-acting C5 complement inhibitor, provides immediate, complete and sustained complement inhibition. The medication works by inhibiting the C5 protein in the terminal complement cascade, a part of the body’s immune system. When activated in an uncontrolled manner, the complement cascade over-responds, leading the body to attack its own healthy cells. ULTOMIRIS is administered intravenously every eight weeks in adult patients, following a loading dose.

ULTOMIRIS is approved in the US, EU, Japan and other countries for the treatment of certain adults with generalized myasthenia gravis (gMG).

ULTOMIRIS is also approved in the US, EU, Japan and other countries for the treatment of certain adults with PNH and for certain children with PNH in the US and EU.

Additionally, ULTOMIRIS is approved in the US, EU, Japan and other countries for certain adults and children with atypical hemolytic uremic syndrome to inhibit complement-mediated thrombotic microangiopathy (aHUS).

Further, ULTOMIRIS is approved in the US, EU and Japan for the treatment of certain adults with neuromyelitis optica spectrum disorder (NMOSD).

As part of a broad development program, ULTOMIRIS is being assessed for the treatment of additional hematology and neurology indications.

**SOLIRIS® (eculizumab)**

SOLIRIS® (eculizumab) is a first-in-class C5 complement inhibitor. The medication works by inhibiting the C5 protein in the terminal complement cascade, a part of the body’s immune system. When activated in an uncontrolled manner, the terminal complement cascade over-responds, leading the body to attack its own healthy cells. SOLIRIS is administered intravenously every two weeks, following an introductory dosing period.

SOLIRIS is approved in the US, EU, Japan, China and other countries for the treatment of patients with PNH
and aHUS.

Additionally, SOLIRIS is approved in Japan and the EU for the treatment of certain adult and pediatric patients with gMG, and in the US, China and other countries for certain adults with gMG.

Further, SOLIRIS is approved in the US, EU, Japan, China and other countries for the treatment of certain adults with NMOSD.

SOLIRIS is not indicated for the treatment of patients with Shiga-toxin E. coli-related hemolytic uremic syndrome.

Alexion

Alexion, AstraZeneca Rare Disease, is the group within AstraZeneca focused on rare diseases, created following the 2021 acquisition of Alexion Pharmaceuticals, Inc. As a leader in rare diseases for more than 30 years, Alexion is focused on serving patients and families affected by rare diseases and devastating conditions through the discovery, development and commercialization of life-changing medicines. Alexion focuses its research efforts on novel molecules and targets in the complement cascade and its development efforts on hematology, nephrology, neurology, metabolic disorders, cardiology and ophthalmology. Headquartered in Boston, Massachusetts, Alexion has offices around the globe and serves patients in 70 countries. For more information, please visit www.alexion.com.

AstraZeneca

AstraZeneca (LSE/STO/Nasdaq: AZN) is a global, science-led biopharmaceutical company that focuses on the discovery, development, and commercialization of prescription medicines in Oncology, Rare Diseases, and BioPharmaceuticals, including Cardiovascular, Renal & Metabolism, and Respiratory & Immunology. Based in Cambridge, UK, AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. Please visit astrazeneca-us.com and follow the Company on social media @AstraZeneca.

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