AstraZeneca advances scientific leadership in hematology at ASH 2023

November 29, 2023

CALQUENCE six-year follow-up data reinforce long-term benefit in chronic lymphocytic leukemia, and data across multiple hematology assets showcase breadth of promising early pipeline

New, longer-term data from ALPHA Phase III trial will further show potential of danicopan to address clinically significant extravascular hemolysis and maintain disease control, allowing paroxysmal nocturnal hemoglobinuria patients to continue standard-of-care treatment with ULTOMIRIS or SOLIRIS

AstraZeneca will present new clinical and real-world data in multiple hematological conditions at the 65th American Society of Hematology (ASH) Annual Meeting and Exposition, December 9 to 12, 2023 in San Diego, CA.

A total of 63 abstracts will feature 14 approved and potential new medicines across the Company's portfolio and pipeline including from Alexion, AstraZeneca's Rare Disease group, in chronic lymphocytic leukemia (CLL) and several types of lymphoma, paroxysmal nocturnal hemoglobinuria (PNH), atypical hemolytic uremic syndrome (aHUS) and amyloid light-chain (AL) amyloidosis.

Anas Younes, Senior Vice President, Hematology R&D, AstraZeneca, said: "Our data at ASH will exemplify how we are advancing a range of innovative modalities including antibody drug conjugates, next-generation immunotherapies and T-cell engagers in hematology. Updated clinical data for AZD0486, our CD19/CD3 T-cell engager, reinforce our belief in this approach as a potential new treatment for lymphoma, and new CALQUENCE data continue to demonstrate long-term efficacy and safety in chronic lymphocytic leukemia with further follow up."

Gianluca Pirozzi, Senior Vice President, Head of Development, Regulatory and Safety, Alexion, said: "Alexion has transformed the treatment landscape and redefined care for the paroxysmal nocturnal hemoglobinuria patient community over the past two decades. At the ASH Annual Meeting, new results from our pivotal ALPHA trial will demonstrate the promise of Factor D inhibition to advance care for the small subset of patients with paroxysmal nocturnal hemoglobinuria who experience clinically significant extravascular hemolysis. We are proud to further our leadership in rare disease by sharing data from our robust hematology pipeline, reflecting our commitment to innovation and improving outcomes for the patients and families we serve."

CALQUENCE® (acalabrutinib) continues to demonstrate long-term benefits in CLL

Six-year follow-up data from the pivotal ELEVATE-TN Phase III trial will further support the continued efficacy, safety and tolerability of CALQUENCE for long-term use in patients with treatment-naïve CLL.[1]

Data from a Phase II trial will show the safety and efficacy of CALQUENCE and rituximab followed by chemotherapy and autologous stem cell transplantation in fit patients with treatment-naïve mantle cell lymphoma (MCL).[2]

An analysis of five prospective CALQUENCE trials, including three randomized, controlled Phase III trials and two non-randomized trials, will show acceptable safety outcomes based on rates of nonfatal and fatal ventricular arrhythmias and sudden death in patients with CLL.[3]

Novel early assets show potential to improve outcomes for blood cancer patients

Data from our early portfolio will demonstrate how the Company is advancing multiple modalities across several scientific platforms, including Immuno-Oncology, Immune-Engagers, Antibody Drug Conjugates (ADCs) and Epigenetics as part of its strategy to attack cancer from multiple angles.

Updated Phase I data for AstraZeneca's CD19/CD3 T-cell engager, AZD0486, will further demonstrate the acceptable safety profile and high response rate of this treatment in relapsed/refractory (R/R) B-cell non-Hodgkin lymphoma (NHL).[4] We will also present the first clinical data on sabestomig, a PD-1/TIM-3 targeting bispecific antibody, in R/R Hodgkin lymphoma, showing encouraging early signals of activity.[5]

The first preclinical data for AZD9829, a novel CD123-targeting ADC, using AstraZeneca's proprietary linker technology to deliver a topoisomerase I inhibitor warhead, will demonstrate promising anti-tumor activity in acute myeloid leukemia.[6] In addition, preclinical data will demonstrate anti-tumor activity of AstraZeneca's novel PRMT5 inhibitor in MTAP silenced Hodgkin lymphoma models. [7]

Showcasing advances to bolster our leadership in PNH with new data on Factor D inhibition and impact of C5 inhibition in long-term disease control

New results from the 24-week and long-term extension period from the pivotal ALPHA Phase III trial will reinforce the potential for danicopan add-on therapy to address clinically significant extravascular hemolysis (EVH) in the small subset of PNH patients who experience this condition while treated with C5 inhibitor therapy, allowing them to maintain control of intravascular hemolysis (IVH) through standard-of-care treatment with ULTOMIRIS® (ravulizumab-cwvz) or SOLIRIS® (eculizumab).[8]

Further, patient-reported outcomes from the ALPHA trial will suggest danicopan as an add-on to ULTOMIRIS or SOLIRIS improved quality of life compared to C5 inhibitor therapy alone in patients with PNH who experience clinically significant EVH.[9]

Additionally, Alexion will present an analysis of six-year outcomes from the Phase III clinical trial evaluating the safety and efficacy of ULTOMIRIS in patients with PNH who did not have previous treatment with a C5 inhibitor.[10] The analysis compared survival against untreated patients in the

International PNH Registry, the largest global real-world database of patients with PNH. Results will suggest ULTOMIRIS improved survival and maintained effective long-term control of IVH, the most significant contributor to morbidity and premature mortality in PNH.[10]

Improving diagnosis and management of life-threatening rare diseases, including amyloidosis

24-month results of a Phase II trial will demonstrate the safety and tolerability of CAEL-101 in combination with cyclophosphamide-bortezomib-dexamethasone with or without daratumumab for the treatment of AL amyloidosis.[11]

Real-world analyses across AL amyloidosis, aHUS and hematopoietic stem cell transplant-associated thrombotic microangiopathy (HSCT-TMA) will also be presented, advancing the scientific understanding of these rare, hematological conditions.[12-16]

Key presentations during the 65th ASH Annual Meeting and Exposition

Lead author	Abstract title	Presentation details
CALQUENCE (acalabrutinib)		
Sharman, JP	Acalabrutinib ± Obinutuzumab vs Obinutuzumab + Chlorambucil in Treatment-naive Chronic Lymphocytic Leukemia: 6-year Follow-up of ELEVATE-TN	Abstract # 636 Oral Session: 642. Chronic Lymphocytic Leukemia: Clinical and Epidemiological: Frontline Treatment with Targeted Agents in Patients with Chronic Lymphocytic Leukemia December 10, 2023 17:45 PST Location: Seaport Ballroom ABCD (Manchester Grand Hyatt San Diego)
Westin, J	Smart Stop: Lenalidomide, Tafasitamab, Rituximab and Acalabrutinib Alone and with Combination Chemotherapy for the Treatment of Newly Diagnosed Diffuse Large B-cell Lymphoma	Abstract # 856 Oral Session: 626. Aggressive Lymphomas: Prospective Therapeutic Trials: Initial Treatment Strategies in Aggressive B-Cell Lymphomas December 11, 2023 15:30 PST Location: Seaport Ballroom ABCD (Manchester Grand Hyatt San Diego)
Hawkes, EA	A Window Study of Acalabrutinib and Rituximab, Followed by Chemotherapy and Autograft (ASCT) in Fit Patients with Treatment-naïve Mantle Cell Lymphoma (MCL): First Report of the Investigator-initiated Australasian Leukemia and Lymphoma Group NHL33 'WAMM' Trial	Abstract # 735 Oral Session: 623. Mantle Cell, Follicular and Other Indolent B-Cell Lymphomas: Clinical and Epidemiological: Prospective Clinical Trials in Mantle Cell Lymphoma Incorporating Novel Agents December 11, 2023 11:00 PST Location: Grand Hall B (Manchester Grand Hyatt San Diego)
Hawkes, EA	TrAVeRse: A Phase 2, Open-Label, Randomized Study of Acalabrutinib in Combination with Venetoclax and Rituximab in Patients with Treatment- naïve Mantle Cell Lymphoma	Abstract # 3054 Poster Session: 623. Mantle Cell, Follicular, and Other Indolent B-Cell Lymphomas: Clinical and Epidemiological: Poster II December 10, 2023 18:00 - 20:00 PST

		Location: Halls G-H (San Diego Convention Center)
Sharman, J	Analysis of Ventricular Arrhythmias and Sudden Death with Acalabrutinib From 5 Prospective Clinical Trials	Abstract # 4643 Poster Session: 642. Chronic Lymphocytic Leukemia: Clinical and Epidemiological: Poster III December 11, 2023 18:00 - 20:00 PST Location: Halls G-H (San Diego Convention Center)
Ferrajoli, A	Cumulative Review of Hypertension in Patients with Chronic Lymphocytic Leukemia (CLL) and Other Hematologic Malignancies Treated with Acalabrutinib: Data from Clinical Trials	Abstract # 1917 Poster Session: 642. Chronic Lymphocytic Leukemia: Clinical and Epidemiological: Poster I December 9, 2023 17:30 - 19:30 PST Location: Halls G-H (San Diego Convention Center)
Sun, C	Extended Follow-Up and Resistance Mutations in CLL Patients Treated with Acalabrutinib	Abstract # 1891 Poster Session: 641. Chronic Lymphocytic Leukemias: Basic and Translational: Poster I December 9, 2023 17:30 - 19:30 PST Location: Halls G-H (San Diego Convention Center)
Jain, P	Acalabrutinib with Rituximab as First-line Therapy for Older Patients with Mantle Cell Lymphoma – A Phase II Clinical Trial	Abstract # 3036 Poster Session: 623. Mantle Cell, Follicular, and Other Indolent B-Cell Lymphomas: Clinical and Epidemiological: Poster II December 10, 2023 18:00 - 20:00 PST Location: Halls G-H (San Diego Convention Center)
Perini, G	ACRUE: A Phase 2, Open-label Study of Acalabrutinib in Combination with Rituximab in Elderly and/or Frail Patients with Treatment-naïve Diffuse Large B-Cell Lymphoma	e-Publication Online Only
AZD0486		
Gaballa, S	Double Step-Up Dosing (2SUD) Regimen Mitigates Severe ICANS and CRS While Maintaining a High Efficacy in Subjects with Relapsed/Refractory (R/R) B-cell Non-Hodgkin Lymphoma (NHL) Treated with AZD0486, a Novel CD19xCD3 T-cell Engager (TCE): Updated Safety and Efficacy Data from the Ongoing First-in-Human (FIH) Phase I Trial	Abstract # 1662 Poster Session: 623. Mantle Cell, Follicular, and Other Indolent B-Cell Lymphomas: Clinical and Epidemiological: Poster I December 9, 2023 17:30 - 19:30 PST Location: Halls G-H (San Diego Convention Center)

AZD9829

Dutta, D	First Disclosure of AZD9829, a TOP1i-ADC Targeting CD123: Promising Preclinical Activity in AML Models with Minimal Effect on Healthy Progenitors	e-Publication Online Only

AZD7789

Mei, M	Safety and Preliminary Efficacy of Sabestomig (AZD7789), an Anti-PD-1 and Anti-TIM-3 Bispecific Antibody, in Patients with Relapsed or Refractory Classical Hodgkin Lymphoma Previously Treated with Anti-PD-(L)1 Therapy	Abstract # 4433 Poster Session: 624. Hodgkin Lymphomas and T/NK cell Lymphomas: Clinical and Epidemiological: Poster III December 11, 2023 18:00 - 20:00 PST Location: Halls G-H (San Diego Convention Center)

PRMT5 inhibitor

Urosevic, J	Epigenetic Silencing of MTAP in Hodgkin's Lymphoma Renders it Sensitive to a 2nd Generation PRMT5 Inhibitor	Abstract # 4185 Poster Session: 605. Molecular Pharmacology and Drug Resistance: Lymphoid Neoplasms: Poster III December 11, 2023 18:00 - 20:00 PST Location: Halls G-H (San Diego Convention Center)

Danicopan

Kulasekararaj, A	Danicopan as Add-On Therapy to Ravulizumab or Eculizumab Versus Placebo in Patients with Paroxysmal Nocturnal Hemoglobinuria and Clinically Significant Extravascular Hemolysis: Phase 3 Long-term Data	Abstract # 576 Oral Session: 508. Bone Marrow Failure: Acquired: Unraveling the Future of PNH Therapy from Clinical Trials December 10, 2023 17:45 PST Location: Room 7 (San Diego Convention Center)
Piatek, C	Patient-reported Outcomes: Danicopan as Add-On Therapy to Ravulizumab or Eculizumab Versus Placebo in Patients with Paroxysmal Nocturnal Hemoglobinuria and Clinically Significant Extravascular Hemolysis	Abstract # 1346 Poster Session: 508. Bone Marrow Failure: Acquired: Poster I December 9, 2023 17:30 - 19:30 PST Location: Halls G-H (San Diego Convention Center)

ULTOMIRIS (ravulizumab-cwvz)

Kulasekararaj, A	Ravulizumab Provides Durable Control of Intravascular Hemolysis and Improves Survival in Patients with Paroxysmal Nocturnal Hemoglobinuria: Long-Term Follow-Up of Study 301 and Comparisons with Patients of the International PNH Registry	Abstract # 2714 Poster Session: 508. Bone Marrow Failure: Acquired: Poster II December 10, 2023 18:00 - 20:00 PST Location: Halls G-H (San Diego Convention Center)
Röth, A	Ravulizumab Effectiveness in the Real-world: Evidence from the International PNH Registry	Abstract # 2722 Poster Session: 508. Bone Marrow Failure: Acquired: Poster II December 10, 2023 18:00 - 20:00 PST Location: Halls G-H (San Diego Convention Center)
Piatek, C	Efficacy and Safety of Subcutaneous Ravulizumab in Patients with Paroxysmal Nocturnal Hemoglobinuria Who Received Prior Intravenous Eculizumab: 2-Year Follow-Up	Abstract # 2713 Poster Session: 508. Bone Marrow Failure: Acquired: Poster II December 10, 2023 18:00 - 20:00 PST Location: Halls G-H (San Diego Convention Center)

CAEL-101

Valent, J	Safety and Tolerability of CAEL-101, an Anti-Amyloid Monoclonal Antibody, Combined with Anti-Plasma Cell Dyscrasia Therapy in Patients with Light-Chain Amyloidosis: 24-Month Results of a Phase 2 Study	Abstract # 540 Oral Session: 654. MGUS, Amyloidosis and Other Non-Myeloma Plasma Cell Dyscrasias: Clinical and Epidemiological: From Light Chain to Fibril–Novel Diagnostics to Treatments for Amyloidosis December 10, 2023 13:15 PST Location: Seaport Ballroom EFGH (Manchester Grand Hyatt San Diego)
Costello, M	CAEL-101 Enhances the Clearance of Light Chain Fibrils and Intermediate Aggregates by Phagocytosis	Abstract # 3307 Poster Session: 651. Multiple Myeloma and Plasma Cell Dyscrasias: Basic and Translational: Poster II December 10, 2023 18:00 - 20:00 PST Location: Halls G-H (San Diego Convention Center)

AL Amyloidosis

Lyons, G	Treatment Patterns and Outcomes for Patients with Light Chain (AL) Amyloidosis: Analysis of a Large US Claims Database	e-Publication Online Only
Thompson, J	Real-world Treatment Patterns Following Update to National Comprehensive Cancer Network Guidelines for Light-Chain Amyloidosis: Results from a US Administrative Claims Database	e-Publication Online Only
Laires, P	Prevalence, Incidence, and Characterization of Light Chain Amyloidosis in the USA: A Real-world Analysis Utilizing Electronic Health Records (EHR)	e-Publication Online Only
aHUS		
Wang, Y	Patient Characteristics and Diagnostic Journey of Thrombotic Microangiopathy Associated with a Trigger: A Real-world, Retrospective, Multi-national Study	e-Publication Online Only
HSCT-TMA		
Wang, Y	Real-World Analysis of the Underdiagnosis, Clinical Outcomes and Associated Burden of Hematopoietic Stem Cell Transplantation-Associated Thrombotic Microangiopathy (HSCT-TMA) in the United States of America	Abstract # 491 Oral Session: 904. Outcomes Research – Non-Malignant Conditions: What to Know: Management Costs and Outcomes in Various Non-Malignant Disorders December 10, 2023 10:30 PST Location: Pacific Ballroom Salons 15-17 (Marriott Marquis San Diego Marina)
PNH		
Wagner-Ballon, O	Neutrophil PNH Type II Cells Are Associated with Thrombosis and Bone Marrow Failure Without Hemolysis: Evidence from Analysis of the 5-year French Nation-Wide Multicenter Observational Study	Abstract # 4083 Poster Session: 508. Bone Marrow Failure: Acquired: Poster III December 11, 2023 18:00 - 20:00 PST Location: Halls G-H (San Diego Convention Center)

INDICATIONS AND USAGE

CALQUENCE is a Bruton tyrosine kinase (BTK) inhibitor indicated for the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy.

This indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

CALQUENCE is also indicated for the treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).

IMPORTANT SAFETY INFORMATION ABOUT CALQUENCE® (acalabrutinib) tablets

Serious and Opportunistic Infections

Fatal and serious infections, including opportunistic infections, have occurred in patients with hematologic malignancies treated with CALQUENCE.

Serious or Grade 3 or higher infections (bacterial, viral, or fungal) occurred in 19% of 1029 patients exposed to CALQUENCE in clinical trials, most often due to respiratory tract infections (11% of all patients, including pneumonia in 6%). These infections predominantly occurred in the absence of

Grade 3 or 4 neutropenia, with neutropenic infection reported in 1.9% of all patients. Opportunistic infections in recipients of CALQUENCE have included, but are not limited to, hepatitis B virus reactivation, fungal pneumonia, Pneumocystis jirovecii pneumonia, Epstein-Barr virus reactivation, cytomegalovirus, and progressive multifocal leukoencephalopathy (PML). Consider prophylaxis in patients who are at increased risk for opportunistic infections. Monitor patients for signs and symptoms of infection and treat promptly.

Hemorrhage

Fatal and serious hemorrhagic events have occurred in patients with hematologic malignancies treated with CALQUENCE. Major hemorrhage (serious or Grade 3 or higher bleeding or any central nervous system bleeding) occurred in 3.0% of patients, with fatal hemorrhage occurring in 0.1% of 1029 patients exposed to CALQUENCE in clinical trials. Bleeding events of any grade, excluding bruising and petechiae, occurred in 22% of patients.

Use of antithrombotic agents concomitantly with CALQUENCE may further increase the risk of hemorrhage. In clinical trials, major hemorrhage occurred in 2.7% of patients taking CALQUENCE without antithrombotic agents and 3.6% of patients taking CALQUENCE with antithrombotic agents. Consider the risks and benefits of antithrombotic agents when co-administered with CALQUENCE. Monitor patients for signs of bleeding.

Consider the benefit-risk of withholding CALQUENCE for 3-7 days pre- and post-surgery depending upon the type of surgery and the risk of bleeding.

Cytopenias

Grade 3 or 4 cytopenias, including neutropenia (23%), anemia (8%), thrombocytopenia (7%), and lymphopenia (7%), developed in patients with hematologic malignancies treated with CALQUENCE. Grade 4 neutropenia developed in 12% of patients. Monitor complete blood counts regularly during treatment. Interrupt treatment, reduce the dose, or discontinue treatment as warranted.

Second Primary Malignancies

Second primary malignancies, including skin cancers and other solid tumors, occurred in 12% of 1029 patients exposed to CALQUENCE in clinical trials. The most frequent second primary malignancy was skin cancer, reported in 6% of patients. Monitor patients for skin cancers and advise protection from sun exposure.

Atrial Fibrillation and Flutter

Grade 3 atrial fibrillation or flutter occurred in 1.1% of 1029 patients treated with CALQUENCE, with all grades of atrial fibrillation or flutter reported in 4.1% of all patients. The risk may be increased in patients with cardiac risk factors, hypertension, previous arrhythmias, and acute infection. Monitor for symptoms of arrhythmia (eg, palpitations, dizziness, syncope, dyspnea) and manage as appropriate.

ADVERSE REACTIONS

The most common adverse reactions (≥20%) of any grade in patients with relapsed or refractory MCL were anemia,* thrombocytopenia,* headache (39%), neutropenia,* diarrhea (31%), fatigue (28%), myalgia (21%), and bruising (21%). The most common Grade ≥3 non-hematological adverse reaction (reported in at least 2% of patients) was diarrhea (3.2%).

*Treatment-emergent decreases (all grades) of hemoglobin (46%), platelets (44%), and neutrophils (36%) were based on laboratory measurements and adverse reactions.

Dose reductions or discontinuations due to any adverse reaction were reported in 1.6% and 6.5% of patients, respectively. Increases in creatinine to 1.5 to 3 times the upper limit of normal (ULN) occurred in 4.8% of patients.

The most common adverse reactions (≥30%) of any grade in patients with CLL were anemia,* neutropenia,* thrombocytopenia,* headache, upper respiratory tract infection, and diarrhea.

*Treatment-emergent decreases (all grades) of hemoglobin, platelets, and neutrophils were based on laboratory measurements and adverse reactions.

In patients with previously untreated CLL exposed to CALQUENCE, fatal adverse reactions that occurred in the absence of disease progression and with onset within 30 days of the last study treatment were reported in 2% for each treatment arm, most often from infection. Serious adverse reactions were reported in 39% of patients in the CALQUENCE plus obinutuzumab arm and 32% in the CALQUENCE monotherapy arm, most often due to events of pneumonia (7% and 2.8%, respectively).

Adverse reactions led to CALQUENCE dose reduction in 7% and 4% of patients in the CALQUENCE plus obinutuzumab arm (N=178) and CALQUENCE monotherapy arm (N=179), respectively. Adverse events led to discontinuation in 11% and 10% of patients, respectively. Increases in creatinine to 1.5 to 3 times ULN occurred in 3.9% and 2.8% of patients in the CALQUENCE combination arm and monotherapy arm, respectively.

In patients with relapsed/refractory CLL exposed to CALQUENCE, serious adverse reactions occurred in 29% of patients. Serious adverse reactions in >5% of patients who received CALQUENCE included lower respiratory tract infection (6%). Fatal adverse reactions within 30 days of the last dose of CALQUENCE occurred in 2.6% of patients, including from second primary malignancies and infection.

Adverse reactions led to CALQUENCE dose reduction in 3.9% of patients (N=154), dose interruptions in 34% of patients, most often due to respiratory tract infections followed by neutropenia, and discontinuation in 10% of patients, most frequently due to second primary malignancies followed by infection. Increases in creatinine to 1.5 to 3 times ULN occurred in 1.3% of patients who received CALQUENCE.

DRUG INTERACTIONS

Strong CYP3A Inhibitors: Avoid co-administration of CALQUENCE with a strong CYP3A inhibitor. If these inhibitors will be used short-term, interrupt CALQUENCE. After discontinuation of strong CYP3A inhibitor for at least 24 hours, resume previous dosage of CALQUENCE.

Moderate CYP3A Inhibitors: Reduce the dosage of CALQUENCE to 100 mg once daily when co-administered with a moderate CYP3A inhibitor.

Strong CYP3A Inducers: Avoid co-administration of CALQUENCE with a strong CYP3A inducer. If co-administration is unavoidable, increase the dosage of CALQUENCE to 200 mg approximately every 12 hours.

SPECIFIC POPULATIONS

Based on findings in animals, CALQUENCE may cause fetal harm and dystocia when administered to a pregnant woman. There are no available data in pregnant women to inform the drug-associated risk. Advise pregnant women of the potential risk to a fetus.

Pregnancy testing is recommended for females of reproductive potential prior to initiating CALQUENCE therapy. Advise female patients of reproductive potential to use effective contraception during treatment with CALQUENCE and for 1 week following the last dose of CALQUENCE.

It is not known if CALQUENCE is present in human milk. Advise lactating women not to breastfeed while taking CALQUENCE and for 2 weeks after the last dose.

Avoid use of CALQUENCE in patients with severe hepatic impairment (Child-Pugh class C). No dosage adjustment of CALQUENCE is recommended in patients with mild (Child-Pugh class A) or moderate (Child-Pugh class B) hepatic impairment.

Please see full Prescribing Information, including Patient Information.

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

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 PNH or aHUS when administered subcutaneously (under your skin).

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 in children.

Subcutaneous administration of ULTOMIRIS has not been evaluated and is not approved for use 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 can lower the ability of your immune system to fight infections.

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

1. You must receive meningococcal vaccines at least 2 weeks before your first dose of ULTOMIRIS if you are not vaccinated.
2. If your healthcare provider decided that urgent treatment with ULTOMIRIS is needed, you should receive meningococcal vaccination as soon as possible.
3. If you have not been vaccinated and ULTOMIRIS therapy must be initiated immediately, you should also receive 2 weeks of antibiotics with your vaccinations.
4. If you had a meningococcal vaccine in the past, you might need additional vaccination. Your healthcare provider will decide if you need additional vaccination.
5. Meningococcal vaccines reduce but 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: headache with nausea or vomiting, headache and fever, headache with a stiff neck or stiff back, fever, fever and a rash, confusion, muscle aches with flu-like symptoms and eyes sensitive to light.

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

ULTOMIRIS is only available through a program called the ULTOMIRIS REMS. Before you can receive ULTOMIRIS, your healthcare provider must: enroll in the ULTOMIRIS REMS program; counsel you about the risk of meningococcal infection; give you information and a Patient Safety Card about the symptoms and your risk of meningococcal infection (as discussed above); and make sure that you are vaccinated with a meningococcal vaccine, and if needed, get revaccinated with the meningococcal vaccine. Ask your healthcare provider if you are not sure if you need to be revaccinated.

ULTOMIRIS may also increase the risk of other types of serious infections. Make sure your child receives vaccinations against Streptococcus pneumoniae and Haemophilus influenzae type b (Hib) if treated with ULTOMIRIS. Call your healthcare provider right away if you have any new signs

or symptoms of infection.

Who should not receive ULTOMIRIS?

Do not receive ULTOMIRIS if you have a meningococcal infection or have not been vaccinated against meningococcal infection unless your healthcare provider decides that urgent treatment with ULTOMIRIS is needed.

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.

ULTOMIRIS can cause serious side effects including allergic reactions to acrylic adhesive. Allergic reactions to the acrylic adhesive may happen with your subcutaneous ULTOMIRIS treatment. If you have an allergic reaction during the delivery of subcutaneous ULTOMIRIS, remove the on-body injector and get medical help right away. Your healthcare provider may treat you with medicines to help prevent or treat allergic reaction symptoms as needed.

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, tiredness, feeling faint, discomfort in your arms or legs, bad taste, or drowsiness. Stop treatment of ULTOMIRIS and tell your healthcare provider or nurse right away if you develop these symptoms, or any other symptoms during your ULTOMIRIS infusion that may mean you are having a serious infusion 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 subcutaneous administration of ULTOMIRIS in adults treated for PNH and aHUS are local injection site reactions.

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.

Read the Instructions for Use that comes with subcutaneous ULTOMIRIS for instructions about the right way to prepare and give your subcutaneous ULTOMIRIS injections through an on-body injector.

Please see the accompanying full Prescribing Information and Medication Guide for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening meningococcal infections/sepsis. Please see the accompanying Instructions for Use for the ULTOMIRIS On Body Delivery System.

INDICATIONS & IMPORTANT SAFETY INFORMATION FOR SOLIRIS® (eculizumab) [injection for intravenous use 300mg/30mL vial]

What is SOLIRIS?

SOLIRIS is a prescription medicine used to treat:

- patients with a disease called Paroxysmal Nocturnal Hemoglobinuria (PNH).
- adults and children with a disease called 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 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 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 can lower the ability of your immune system to fight infections.

- **SOLIRIS increases your chance of getting serious and life-threatening meningococcal infections that may quickly become life-threatening and cause death if not recognized and treated early.**
- You must receive meningococcal vaccines at least 2 weeks before your first dose of SOLIRIS if you are not vaccinated.
- If your doctor decided that urgent treatment with SOLIRIS is needed, you should receive meningococcal vaccination as soon as possible.
- If you have not been vaccinated and SOLIRIS therapy must be initiated immediately, you should also receive 2 weeks of antibiotics with your vaccinations.
- If you had a meningococcal vaccine in the past, you might need additional vaccination. Your doctor will decide if you need additional vaccination.
- Meningococcal vaccines reduce but do not prevent all meningococcal infections. Call your doctor or get emergency medical care right away if you get any of these signs and symptoms of a meningococcal infection: headache with nausea or vomiting, headache and fever, headache with a stiff neck or stiff back, fever, fever and a rash, confusion, muscle aches with flu-like symptoms, and eyes sensitive to light.

Your doctor will give you a Patient Safety Card about the risk of meningococcal infection. Carry it with you at all times during treatment and for 3 months after your last SOLIRIS dose. It is important to show this card to any doctor or nurse to help them diagnose and treat you quickly.

SOLIRIS is only available through a program called the SOLIRIS REMS. Before you can receive SOLIRIS, your doctor must enroll in the SOLIRIS REMS program; counsel you about the risk of meningococcal infection; give you information and a Patient Safety Card about the symptoms and your risk of meningococcal infection (as discussed above); and make sure that you are vaccinated with the meningococcal vaccine and, if needed, get revaccinated with the meningococcal vaccine. Ask your doctor if you are not sure if you need to be revaccinated.

SOLIRIS may also increase the risk of other types of serious infections. Make sure your child receives vaccinations 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 meningococcal infection or have not been vaccinated against meningitis infection unless your doctor decides that urgent treatment with SOLIRIS is needed.

Before you receive SOLIRIS, tell your doctor 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 doctor 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. It is important that you have all recommended vaccinations before you start SOLIRIS, receive 2 weeks of antibiotics if you immediately start SOLIRIS, and stay up-to-date with all recommended vaccinations during treatment with SOLIRIS.

If you have PNH, your doctor 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 doctor will need to monitor you closely during and for at least 12 weeks after stopping treatment 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 doctor 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 doctor may need to infuse SOLIRIS more slowly, or stop SOLIRIS.

The most common side effects in people with PNH treated with SOLIRIS include: headache, pain or swelling of your nose or throat (nasopharyngitis), back pain, and nausea.

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 doctor 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 doctor or pharmacist. Call your doctor for medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit MedWatch, or call 1-800-FDA-1088.

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

Notes

CALQUENCE® (acalabrutinib)

CALQUENCE® (acalabrutinib) is a next-generation, selective inhibitor of Bruton's tyrosine kinase (BTK). CALQUENCE binds covalently to BTK, thereby inhibiting its activity.[17,18] In B cells, BTK signaling results in activation of pathways necessary for B-cell proliferation, trafficking, chemotaxis and adhesion.

CALQUENCE has been used to treat 50,000 patients worldwide and is approved in the US for the treatment of CLL and SLL and for the treatment of adult patients with MCL who have received at least one prior therapy.[17] CALQUENCE is approved for CLL in the EU and many other countries worldwide and approved in Japan for relapsed or refractory CLL and SLL.
As part of an extensive clinical development program, AstraZeneca is currently evaluating CALQUENCE in more than 20 company-sponsored clinical trials. CALQUENCE is being evaluated for the treatment of multiple B-cell blood cancers, including CLL, MCL, diffuse large B-cell lymphoma, Waldenström's macroglobulinemia, marginal zone lymphoma and other hematologic malignancies.

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 and Japan for the treatment of certain adults with generalized myasthenia gravis (gMG).

ULTOMIRIS is also approved in the US, EU and Japan 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 and Japan for certain adults and children with aHUS to inhibit complement-mediated thrombotic microangiopathy.

Further, ULTOMIRIS is approved in the 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 and China 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 and China for certain adults with gMG.

Further, SOLIRIS is approved in the US, EU, Japan and China 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.

AstraZeneca in hematology
AstraZeneca is pushing the boundaries of science to redefine care in hematology. We have expanded our commitment to patients with hematologic conditions, not only in oncology but also in rare diseases with the acquisition of Alexion, allowing us to reach more patients with high unmet needs. By applying our deep understanding of blood cancers, leveraging our strength in solid tumor oncology and delivering on Alexion's pioneering legacy in complement science to provide innovative medicines for rare diseases, we are pursuing the end-to-end development of novel therapies designed to target underlying drivers of disease.

By targeting hematologic conditions with high unmet medical needs, we aim to deliver innovative medicines and approaches to improve patient outcomes. Our goal is to help transform the lives of patients living with malignant, rare and other related hematologic diseases, shaped by insights from patients, caregivers and physicians to have the most meaningful impact.

AstraZeneca in oncology
AstraZeneca is leading a revolution in oncology with the ambition to provide cures for cancer in every form, following the science to understand cancer and all its complexities to discover, develop and deliver life-changing medicines to patients.

The Company's focus is on some of the most challenging cancers. It is through persistent innovation that AstraZeneca has built one of the most diverse portfolios and pipelines in the industry, with the potential to catalyze changes in the practice of medicine and transform the patient experience.

AstraZeneca has the vision to redefine cancer care and, one day, eliminate cancer as a cause of death.

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 more than 50 countries.

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 www.astrazeneca-us.com and follow the Company on social media @AstraZeneca.

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