News Release

AstraZeneca showcases strength of hematology portfolio and pipeline across multiple hard-to-treat conditions at ASH 2022

CALQUENCE real-world evidence and long-term follow-up data, as well as research collaborations, will reinforce efficacy and safety across B-cell malignancies

Early clinical data will illustrate potential of multiple pipeline molecules, including TNB-486 (AZD0486), across hematologic malignancies

Research from Alexion, AstraZeneca Rare Disease, offers new insights to accelerate innovation and improve time to diagnosis for several rare diseases

WILMINGTON, Del., November 30, 2022 – AstraZeneca will present 47 abstracts showcasing new data from across its hematology portfolio and clinical pipeline, demonstrating its commitment to redefining care for hard-to-treat blood diseases at the 64th American Society of Hematology (ASH) Annual Meeting and Exposition, December 10 to 13, 2022.

A total of eight approved and potential new medicines will be featured across more than 10 types of blood cancers and rare diseases, including data in chronic lymphocytic leukemia (CLL), follicular lymphoma (FL), diffuse large B-cell lymphoma (DLBCL), mantle cell lymphoma (MCL), paroxysmal nocturnal hemoglobinuria (PNH), atypical hemolytic uremic syndrome (aHUS) and amyloid light chain (AL) amyloidosis.

Anas Younes, Senior Vice President, Oncology R&D, AstraZeneca, said: “At this year’s ASH Annual Meeting, our data demonstrate the broad potential of our hematology pipeline and the continued strength of our approved medicines. Data are being highlighted from many of our early-stage molecules, including clinical trials of TNB-486 (AZD0486), a B-cell targeting T-cell engager, and presentations of long-term follow-up data will show the consistent safety and efficacy profile of CALQUENCE.”

Gianluca Pirozzi, Senior Vice President, Head of Development and Safety, Alexion, AstraZeneca Rare Disease said: “The depth and breadth of Alexion data at this year’s ASH Annual Meeting reinforce the importance of earlier diagnosis and disease management for rare diseases that are often not well-understood. We will share research across several therapy areas – including an oral presentation demonstrating the potential of vemircopan, an investigational, second-generation factor D inhibitor as monotherapy treatment of paroxysmal nocturnal hemoglobinuria – underscoring our leadership and unwavering commitment to driving critical innovations in rare disease.”

CALQUENCE® (acalabrutinib) real-world evidence and long-term follow-up data support consistent efficacy and safety profile

- A post-hoc safety analysis from the head-to-head ELEVATE-RR Phase III trial of CALQUENCE versus ibrutinib will further support tolerability differences of CALQUENCE in relapsed or refractory CLL.[1]
- Final long-term follow-up results of the Phase I/II trials evaluating CALQUENCE monotherapy in front-line and relapsed or refractory CLL will further support the continued efficacy and safety CALQUENCE demonstrated in both settings.[2,3]

- An oral presentation of Phase II research sponsored by the Dana-Farber Cancer Institute will show the efficacy and tolerability of CALQUENCE combined with venetoclax and obinutuzumab in a front-line, high-risk CLL population.[4]
- A retrospective pooled analysis will show the benefit of adding obinutuzumab to CALQUENCE in the front-line CLL setting in patients with select genomic characteristics.[5]
- An oral presentation of preliminary Phase II results sponsored by Weill Cornell Medicine will show that CALQUENCE combined with lenalidomide and rituximab is generally well-tolerated, highly effective and produces high rates of minimal residual disease-negative complete remission in front-line MCL.[6]

Novel treatment strategies with emerging pipeline molecules exhibit therapeutic potential

- An oral presentation of interim Phase I results evaluating TNB-486 (AZD0486), a CD19/CD3 next generation bispecific T-cell engager, will show the potential of targeting CD19/CD3, leading to an increase in anti-cancer activity in heavily pretreated patients with B-cell non-Hodgkin lymphoma (NHL).[7]
- Results from Phase I and II trials of CDK9 inhibitor AZD4573 alone and with CALQUENCE will exhibit data on tolerability across a broad range of hematologic malignancies, including relapsed or refractory DLBCL.[8,9]
- Preliminary results from an ongoing Phase I trial will demonstrate that Bcl-2/Bcl-xl inhibitor AZD0466 has been well-tolerated in patients with advanced hematologic malignancies.[10]

Innovating to help address the treatment needs of all patients with PNH

- An oral presentation detailing interim results from a Phase II open-label trial of vemircopan (ALXN2050) will highlight efficacy and safety data from the treatment-naïve patient group, establishing proof-of-concept as a monotherapy for PNH.[11]
- An interim analysis from an ongoing Phase IV trial assessing the impact of switching to standard, weight-based intravenous (i.v.) ULTOMIRIS® (ravulizumab-cwvz) from high-dose i.v. SOLIRIS® (eculizumab) in adults with PNH will be presented.[12]

Improving diagnosis and management of life-threatening rare diseases

- An analysis of data from the Global aHUS Registry, which contains information on patients across more than 100 sites in more than 20 countries, will highlight the importance of considering aHUS as a diagnosis even in the presence of a triggering condition or associated event.[13]
- An analysis of real-world patient data from the US Premier Healthcare Database will expand on the potential of the PLASMIC scoring system to aid in identifying people with aHUS and making earlier treatment decisions.[14]
- An analysis of pediatric patients with hematopoietic stem cell transplant-associated thrombotic microangiopathy (HSCT-TMA) will provide insights on the correlation between complement activation and endothelial damage in HSCT-TMA and the potential for useful biomarkers indicative of this damage to inform diagnosis.[15]
- Results through one year on safety, tolerability and biomarker data will be presented from a Phase II trial evaluating CAEL-101, a potentially first-in-class monoclonal antibody, in adults with AL amyloidosis.[16]

- A real-world analysis in a current population with AL amyloidosis using Komodo Health US claims data will highlight the need for greater awareness and understanding to accelerate time to diagnosis.[17]

Key presentations during the 64th ASH Annual Meeting and Exposition

Lead author	Abstract title	Presentation details
CALQUENCE (acalabrutinib)		
Byrd, J	Final Results of the Phase 1/2 Study of Acalabrutinib Monotherapy in Treatment-Naive Chronic Lymphocytic Leukemia with >6 Years of Follow-Up	Abstract # 4431 Poster Session: 642. Chronic Lymphocytic Leukemia: Clinical and Epidemiological: Poster III December 12, 2022 18:00-20:00 CST Location: Hall D (Ernest N. Morial Convention Center)
Davids, MS	Contribution of Obinutuzumab to Acalabrutinib Therapy in Patients with Treatment-Naive Chronic Lymphocytic Leukemia: Analysis of Survival Outcomes by Genomic Features	Abstract # 1815 Poster Session: 642. Chronic Lymphocytic Leukemia: Clinical and Epidemiological: Poster I December 10, 2022 17:30-19:30 CST Location: Hall D (Ernest N. Morial Convention Center)
Davies, AJ	Durable Responses from Acalabrutinib in Combination with Rituximab, Cyclophosphamide, Doxorubicin, Vincristine and Prednisolone (R-CHOP) as First Line Therapy for Patients with Diffuse Large B-Cell Lymphoma (DLBCL): The ACCEPT Phase Ib/II Single Arm Study	Abstract # 4265 Poster Session: 626. Aggressive Lymphomas: Prospective Therapeutic Trials: Poster III December 12, 2022 18:00-20:00 CST Location: Hall D (Ernest N. Morial Convention Center)
Furman, R	Phase 1/2 Study of Acalabrutinib Monotherapy in Patients with Relapsed/Refractory Chronic Lymphocytic Leukemia: Final Results with >4 Years of Follow-Up	Abstract # 4434 Poster Session: 642. Chronic Lymphocytic Leukemia: Clinical and Epidemiological: Poster III December 12, 2022 18:00-20:00 CST Location: Hall D (Ernest N. Morial Convention Center)
Ruan, J	Phase 2 Trial of Acalabrutinib-Lenalidomide-Rituximab (ALR) with Real-Time Monitoring of MRD in Patients with Treatment-Naïve Mantle Cell Lymphoma	Abstract # 73 Oral Session: 623. Mantle Cell, Follicular, and Other Indolent B Cell Lymphomas: Clinical and Epidemiological I December 10, 2022 9:30 CST Location: La Nouvelle Orleans Ballroom C (Ernest N. Morial Convention Center)
Ryan, CE	Updated Results from a Multicenter, Phase 2 Study of Acalabrutinib, Venetoclax, Obinutuzumab (AVO) in a Population of Previously Untreated Patients with CLL Enriched for High-Risk Disease	Abstract # 344 Oral Session: 642. Chronic Lymphocytic Leukemia: Clinical and Epidemiological: Targeted Triplet Combinations and Richter's Transformation December 10, 2022 16:15 CST Location: R06-R09 (Ernest N. Morial Convention Center)
Seymour, JF	Assessing the Burden of Adverse Events in a Head-to-Head Trial of Acalabrutinib Versus Ibrutinib in Previously Treated Chronic Lymphocytic Leukemia (CLL)	Abstract # 3133 Poster Session: 642. Chronic Lymphocytic Leukemia: Clinical and Epidemiological: Poster II

		December 11, 2022 18:00-20:00 CST Location: Hall D (Ernest N. Morial Convention Center)
AZD0486 (CD19/CD3 T-cell engager)		
Hou, JZ	Interim Results of the Phase 1 Study of Tnb-486, a Novel CD19xCD3 T-Cell Engager, in Patients with Relapsed/Refractory (R/R) B-NHL	Abstract # 612 Oral Session: 623. Mantle Cell, Follicular, and Other Indolent B Cell Lymphomas: Clinical and Epidemiological IV December 11, 2022 17:45 CST Location: 278-282 (Ernest N. Morial Convention Center)
AZD0466 (Bcl-2/Bcl-xL inhibitor)		
Arslan, S	Safety and Tolerability of AZD0466 as Monotherapy for Patients with Advanced Hematological Malignancies. Preliminary Results from an Ongoing Phase I/II Trial	Abstract # 4094 Poster Session: 616. Acute Myeloid Leukemias: Investigational Therapies, Excluding Transplantation and Cellular Immunotherapies: Poster III December 12, 2022 18:00-20:00 CST Location: Hall D (Ernest N. Morial Convention Center)
AZD4573 (CDK9 inhibitor)		
Brümmendorf, T	Safety, Tolerability, Pharmacokinetics (PK) and Preliminary Antitumor Activity of the Cyclin-Dependent Kinase-9 (CDK9) Inhibitor AZD4573 in Relapsed/Refractory Hematological Malignancies: A Phase 1 First-in-Human Study	Abstract # 1353 Poster Session: 605. Molecular Pharmacology and Drug Resistance: Lymphoid Neoplasms: Poster I December 10, 2022 17:30-19:30 CST Location: Hall D (Ernest N. Morial Convention Center)
Strati, P	Phase 1b/2a Study of AZD4573 (CDK9i) and Acalabrutinib in Patients with Relapsed/Refractory Diffuse Large B-Cell Lymphoma (r/r DLBCL): Results from Dose-Escalation	Abstract # 2962 Poster Session: 627. Aggressive Lymphomas: Clinical and Epidemiological: Poster II December 11, 2022 18:00-20:00 CST Location: Hall D (Ernest N. Morial Convention Center)
VEMIRCOPAN (ALXN2050)		
Browett, P	Vemircopan (ALXN2050) Monotherapy in Paroxysmal Nocturnal Hemoglobinuria: Interim Data from a Phase 2 Open-Label Proof-of-Concept Study	Abstract # 294 Oral Session: 508. Bone Marrow Failure: Acquired: Clinical Studies December 10, 2022 17:15 CST Location: 260-262 (Ernest N. Morial Convention Center)
ULTOMIRIS (ravulizumab-cwvz)		
Griffin, M	Terminal Complement Inhibition and Control of Hemolysis in Paroxysmal Nocturnal Hemoglobinuria Following Switching from High-Dose Eculizumab to Ravulizumab: An Interim Analysis	Abstract # 1251 Poster Session: 508. Bone Marrow Failure: Acquired: Poster I December 10, 2022 17:30-19:30 CST Location: Hall D (Ernest N. Morial Convention Center)
ALXN1820		
Dai, Y	A Phase 2a, Randomized, Open-Label Study to Evaluate Multiple Dosing Regimens of Subcutaneous ALXN1820 in Adult Patients with Sickle Cell Disease	Abstract # 3713 Poster Session: 114. Hemoglobinopathies, Excluding

		Thalassemia: Clinical and Epidemiological: Poster III December 12, 2022 18:00-20:00 CST Location: Hall D (Ernest N. Morial Convention Center)
CAEL-101		
Valent, J	1-Year Results from a Phase 2 Study to Determine Safety and Tolerability of Treating Patients with Light-Chain (AL) Amyloidosis with CAEL-101, an Anti-Amyloid Monoclonal Antibody, Combined with Anti-Plasma Cell Dyscrasia	Abstract # 4550 Poster Session: 653. Myeloma and Plasma Cell Dyscrasias: Prospective Therapeutic Trials: Poster III December 12, 2022 18:00-20:00 CST Location: Hall D (Ernest N. Morial Convention Center)
AL Amyloidosis		
Catini, J	Evaluation of the Path to Diagnosis and Time to Treatment in Patients with Light-Chain Amyloidosis Using the Komodo Claims Database	Abstract # 1887 Poster Session: 652. Multiple Myeloma and Plasma Cell Dyscrasias: Clinical and Epidemiological: Poster I December 10, 2022 17:30-19:30 CST Location: Hall D (Ernest N. Morial Convention Center)
HSCT-TMA		
Jacobi, P	Complement Activation is Associated with Endothelial Damage in Hematopoietic Stem Cell Transplant Associated-Thrombotic Microangiopathy	Abstract # 2431 Poster Session: 301. Vasculature, Endothelium, Thrombosis and Platelets: Basic and Translational: Poster II December 11, 2022 18:00-20:00 CST Location: Hall D (Ernest N. Morial Convention Center)
aHUS		
Gasteyger, C	Use of PLASMIC Scores to Aid Diagnosis of aHUS: A Real-World Analysis of Hospitalized Patients from the Premier Healthcare Database	Abstract # 1178 Poster Session: 331. Thrombotic Microangiopathies/Thrombocytopenias and COVID-19-related Thrombotic/Vascular Disorders: Clinical and Epidemiological: Poster I December 10, 2022 17:30-19:30 CST Location: Hall D (Ernest N. Morial Convention Center)
Siedlecki, A	Characterization of Patients with aHUS and Triggering/Associated Events, with and without Complement Pathogenic Variants or anti-CFH Antibodies: A Global aHUS Registry Analysis	Abstract # 1173 Poster Session: 331. Thrombotic Microangiopathies/Thrombocytopenias and COVID-19-related Thrombotic/Vascular Disorders: Clinical and Epidemiological: Poster I December 10, 2022 17:30-19:30 CST Location: Hall D (Ernest N. Morial Convention Center)

INDICATION 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 jiroveci 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.

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INDICATION(S) & IMPORTANT SAFETY INFORMATION for ULTOMIRIS

INDICATION(S)

Paroxysmal Nocturnal Hemoglobinuria (PNH)

ULTOMIRIS is indicated for the treatment of adult and pediatric patients one month of age and older with paroxysmal nocturnal hemoglobinuria (PNH).

Atypical Hemolytic Uremic Syndrome (aHUS)

ULTOMIRIS is indicated for the treatment of adult and pediatric patients one month of age and older with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy (TMA).

Limitation of Use:

ULTOMIRIS is not indicated for the treatment of patients with Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS).

Subcutaneous Use in Adult Patients with PNH or aHUS

Subcutaneous administration of ULTOMIRIS is not approved for use in pediatric patients.

IMPORTANT SAFETY INFORMATION

WARNING: SERIOUS MENINGOCOCCAL INFECTIONS

Life-threatening meningococcal infections/sepsis have occurred in patients treated with ULTOMIRIS. Meningococcal infection may become rapidly life-threatening or fatal if not recognized and treated early.

- **Comply with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for meningococcal vaccination in patients with complement deficiencies.**
- **Immunize patients with meningococcal vaccines at least 2 weeks prior to administering the first dose of ULTOMIRIS, unless the risks of delaying ULTOMIRIS therapy outweigh the risk of developing a meningococcal infection. See *Warnings and Precautions* for additional guidance on the management of the risk of meningococcal infection.**
- **Vaccination reduces, but does not eliminate, the risk of meningococcal infections. Monitor patients for early signs of meningococcal infections and evaluate immediately if infection is suspected.**

Because of the risk of serious meningococcal infections, ULTOMIRIS is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called ULTOMIRIS REMS.

CONTRAINDICATIONS

- Patients with unresolved *Neisseria meningitidis* infection.
- Patients who are not currently vaccinated against *Neisseria meningitidis*, unless the risks of delaying ULTOMIRIS treatment outweigh the risks of developing a meningococcal infection.

WARNINGS AND PRECAUTIONS

Serious Meningococcal Infections

Life-threatening meningococcal infections have occurred in patients treated with ULTOMIRIS. The use of ULTOMIRIS increases a patient's susceptibility to serious meningococcal infections (septicemia and/or meningitis). Meningococcal disease due to any serogroup may occur.

Vaccinate or revaccinate for meningococcal disease according to the most current ACIP recommendations for patients with complement deficiencies. Immunize patients without history of meningococcal vaccination at least 2 weeks prior to the first dose of ULTOMIRIS. Patients who initiate ULTOMIRIS treatment less than 2 weeks after receiving meningococcal vaccine(s) must receive appropriate prophylactic antibiotics until 2 weeks after vaccination.

In clinical studies, 59 adult patients with PNH and 2 adult patients with gMG were treated with ULTOMIRIS less than 2 weeks after meningococcal vaccination. All of these patients received antibiotics for prophylaxis of meningococcal infection until at least 2 weeks after meningococcal vaccination. The benefits and risks of antibiotic prophylaxis for prevention of meningococcal infections in patients receiving ULTOMIRIS have not been established. In clinical studies with ULTOMIRIS, <1% of patients developed serious meningococcal infections/sepsis while receiving treatment with ULTOMIRIS. All were adult patients with PNH who had been vaccinated. These patients recovered while continuing treatment with ULTOMIRIS. Consider discontinuation of ULTOMIRIS in patients who are undergoing treatment for serious meningococcal infection.

ULTOMIRIS REMS
Due to the risk of meningococcal infections, ULTOMIRIS is available only through a restricted program under a REMS called ULTOMIRIS REMS.

Under the ULTOMIRIS REMS, prescribers must enroll in the program. Prescribers must counsel patients about the risk of meningococcal infection/sepsis, provide the patients with the REMS educational materials, and ensure patients are vaccinated with meningococcal vaccines.

Additional information on the REMS requirements is available at www.ultomirisrems.com or 1-888-765-4747.

Other Infections
Patients may have increased susceptibility to infections, especially with encapsulated bacteria, such as infections caused by *Neisseria meningitidis* but also *Streptococcus pneumoniae*, *Haemophilus influenzae*, and to a lesser extent, *Neisseria gonorrhoeae*. Children treated with ULTOMIRIS may be at increased risk of developing serious infections due to *Streptococcus pneumoniae* and *Haemophilus influenzae* type b (Hib). Administer vaccinations for the prevention of *Streptococcus pneumoniae* and *Haemophilus influenzae* type b (Hib) infections according to ACIP guidelines. If ULTOMIRIS is administered to patients with active systemic infections, monitor closely for worsening infection.

Monitoring Disease Manifestations after ULTOMIRIS Discontinuation
Treatment Discontinuation for PNH
After discontinuing treatment with ULTOMIRIS, closely monitor for signs and symptoms of hemolysis, identified by elevated LDH along with sudden decrease in PNH clone size or hemoglobin, or re-appearance of symptoms such as fatigue, hemoglobinuria, abdominal pain, shortness of breath (dyspnea), major adverse vascular event (including thrombosis), dysphagia, or erectile dysfunction. Monitor any patient who discontinues ULTOMIRIS for at least 16 weeks to detect hemolysis and other reactions. If signs and symptoms of hemolysis occur after discontinuation, including elevated LDH, consider restarting treatment with ULTOMIRIS.

Treatment Discontinuation for aHUS

ULTOMIRIS treatment of aHUS should be a minimum duration of 6 months. Due to heterogeneous nature of aHUS events and patient-specific risk factors, treatment duration beyond the initial 6 months should be individualized. There are no specific data on ULTOMIRIS discontinuation. After discontinuing treatment with ULTOMIRIS, patients should be monitored for clinical symptoms and laboratory signs of TMA complications for at least 12 months.

TMA complications post-discontinuation can be identified if any of the following is observed: Clinical symptoms of TMA include changes in mental status, seizures, angina, dyspnea, thrombosis or increasing blood pressure. In addition, at least two of the following laboratory signs observed concurrently and results should be confirmed by a second measurement 28 days apart with no interruption: a decrease in platelet count of 25% or more as compared to either baseline or to peak platelet count during ULTOMIRIS treatment; an increase in serum creatinine of 25% or more as compared to baseline or to nadir during ULTOMIRIS treatment; or, an increase in serum LDH of 25% or more as compared to baseline or to nadir during ULTOMIRIS treatment. If TMA complications occur after discontinuation, consider reinitiation of ULTOMIRIS treatment or appropriate organ-specific supportive measures.

Thromboembolic Event Management

The effect of withdrawal of anticoagulant therapy during treatment with ULTOMIRIS has not been established. Treatment should not alter anticoagulant management.

Infusion-Related Reactions

Intravenous or subcutaneous administration of ULTOMIRIS may result in systemic infusion-related reactions, including anaphylaxis and hypersensitivity reactions. In clinical trials, infusion-related reactions occurred in approximately 1% of patients treated with ULTOMIRIS. These events included lower back pain, drop in blood pressure, elevation in blood pressure, limb discomfort, drug hypersensitivity (allergic reaction), dysgeusia (bad taste), and drowsiness. These reactions did not require discontinuation of ULTOMIRIS. If signs of cardiovascular instability or respiratory compromise occur, interrupt ULTOMIRIS infusion and institute appropriate supportive measures.

Injection Site Reactions- Subcutaneous administration

27% (23/84) of patients treated with subcutaneous administration of ULTOMIRIS experienced injection site reactions which included application site rash, device allergy, infusion site pain, infusion site reaction, injection site bruising, injection site erythema, injection site hematoma, injection site induration, injection site inflammation, injection site pain, injection site pruritus, injection site rash, injection site reaction, injection site swelling, injection site urticaria, medical device site bruise, medical device site erythema, medical device site hematoma, medical device site induration, medical device site pruritus, medical device site rash, and medical device site reaction.

Allergies to Acrylic Adhesives

The on-body injector of ULTOMIRIS uses acrylic adhesive. For patients with a known allergy to acrylic adhesive, use of this product may result in an allergic reaction. Premedication can be considered, and supportive measures should be instituted if signs of allergy appear.

ADVERSE REACTIONS

Adverse Reactions for PNH

Adverse reactions reported in 5% or more of patients treated with ULTOMIRIS vs. Eculizumab was Upper respiratory tract infection (39% vs. 39%), Headache (32% vs. 26%), Diarrhea (9% vs. 5%), Nausea (9% vs. 9%), Pyrexia (7% vs. 8%), Pain in extremity (6% vs. 5%), Abdominal pain (6% vs. 7%), Dizziness (5% vs. 6%), Arthralgia (5% vs. 5%). Serious adverse reactions were reported in 15 (6.8%) patients receiving ULTOMIRIS. The serious adverse reactions in

patients treated with ULTOMIRIS included hyperthermia and pyrexia. No serious adverse reaction was reported in more than 1 patient treated with ULTOMIRIS. One fatal case of sepsis was identified in a patient treated with ULTOMIRIS. In clinical studies, clinically relevant adverse reactions in 1% of adult patients include infusion-related reactions.

Adverse reactions reported in 10% or more of pediatric patients treated with ULTOMIRIS who were treatment-naïve vs. Eculizumab-experienced was Anemia (20% vs. 25%), Abdominal pain (0% vs. 38%), Constipation (0% vs. 25%), Pyrexia (20% vs. 13%), Upper respiratory tract infection (20% vs. 75%), Pain in extremity (0% vs. 25%), Headache (20% vs. 25%).

Adverse Reactions for aHUS
Most common adverse reactions in patients with aHUS (incidence ≥20%) were upper respiratory tract infection, diarrhea, nausea, vomiting, headache, hypertension and pyrexia. Serious adverse reactions were reported in 42 (57%) patients with aHUS receiving ULTOMIRIS. The most frequent serious adverse reactions reported in more than 2 patients (2.7%) treated with ULTOMIRIS were hypertension, pneumonia and abdominal pain. In clinical studies, clinically relevant adverse reactions in <10% of patients include viral tonsillitis in adults and viral infection in pediatric patients and in 3% of adult patients include infusion-related reactions.

Adverse Reactions for Subcutaneous Administration of ULTOMIRIS
Most common adverse reactions (≥10%) with ULTOMIRIS subcutaneous administration via On Body Injector in adult patients with PNH were local injection site reactions, diarrhea, and headache.

DRUG INTERACTIONS
Plasma Exchange, Plasmapheresis, and Intravenous Immunoglobulins
Concomitant use of ULTOMIRIS with plasma exchange (PE), plasmapheresis (PP), or intravenous immunoglobulin (IVIg) treatment can reduce serum ravulizumab concentrations and requires a supplemental dose of ULTOMIRIS.

Neonatal Fc Receptor Blockers
Concomitant use of ULTOMIRIS with neonatal Fc receptor (FcRn) blockers (e.g., efgartigimod) may lower systemic exposures and reduce effectiveness of ULTOMIRIS. Closely monitor for reduced effectiveness of ULTOMIRIS.

Please see accompanying full Prescribing Information for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening meningococcal infections/sepsis.

INDICATIONS & IMPORTANT SAFETY INFORMATION FOR SOLIRIS® (eculizumab)

INDICATIONS

Paroxysmal Nocturnal Hemoglobinuria (PNH)
Soliris is indicated for the treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis.

Atypical Hemolytic Uremic Syndrome (aHUS)
Soliris is indicated for the treatment of patients with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy.

Limitation of Use
Soliris is not indicated for the treatment of patients with Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS).

IMPORTANT SAFETY INFORMATION

WARNING: SERIOUS MENINGOCOCCAL INFECTIONS

Life-threatening and fatal meningococcal infections have occurred in patients treated with Soliris
and may become rapidly life-threatening or fatal if not recognized and treated early.

- **Comply with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for meningococcal vaccination in patients with complement deficiencies.**
- **Immunize patients with meningococcal vaccines at least 2 weeks prior to administering the first dose of Soliris, unless the risks of delaying Soliris therapy outweigh the risk of developing a meningococcal infection. (See *Serious Meningococcal Infections* for additional guidance on the management of the risk of meningococcal infection).**
- **Vaccination reduces, but does not eliminate, the risk of meningococcal infections. Monitor patients for early signs of meningococcal infections and evaluate immediately if infection is suspected.**

Soliris is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS). Under the Soliris REMS, prescribers must enroll in the program. Enrollment in the Soliris REMS program and additional information are available by telephone: 1-888-SOLIRIS (1-888-765-4747) or at www.solirisrems.com.

Contraindications
- Patients with unresolved serious *Neisseria meningitidis* infection
- Patients who are not currently vaccinated against *Neisseria meningitidis*, unless the risks of delaying Soliris treatment outweigh the risks of developing a meningococcal infection

Warnings and Precautions

Serious Meningococcal Infections
Risk and Prevention

The use of Soliris increases a patient's susceptibility to serious meningococcal infections (septicemia and/or meningitis).

Vaccinate or revaccinate for meningococcal disease according to the most current ACIP recommendations for patients with complement deficiencies. Immunize patients without a history of meningococcal vaccination at least 2 weeks prior to receiving the first dose of Soliris. If Soliris must be initiated immediately in an unvaccinated patient, administer meningococcal vaccine(s) as soon as possible and provide 2 weeks of antibacterial drug prophylaxis. Discontinue Soliris in patients who are undergoing treatment for serious meningococcal infections.

REMS
Prescribers must counsel patients about the risk of meningococcal infection, provide the patients with the REMS educational materials, and ensure patients are vaccinated with meningococcal vaccine(s).

Other Infections
Serious infections with *Neisseria* species (other than *N. meningitidis*), including disseminated gonococcal infections, have been reported.

Patients may have increased susceptibility to infections, especially with encapsulated bacteria. Additionally, *Aspergillus* infections have occurred in immunocompromised and neutropenic patients. Children treated with Soliris may be at increased risk of developing serious infections due to *Streptococcus pneumoniae* and *Haemophilus influenzae* type b (Hib). Administer vaccinations for the prevention of *Streptococcus pneumoniae* and *Haemophilus influenzae* type b (Hib) infections according to ACIP guidelines. Use caution when administering Soliris to patients with any systemic infection.

Monitoring Disease Manifestations After Soliris Discontinuation
Treatment Discontinuation for PNH
Monitor patients after discontinuing Soliris for at least 8 weeks to detect hemolysis.

Treatment Discontinuation for aHUS
After discontinuing Soliris, monitor patients with aHUS for signs and symptoms of thrombotic microangiopathy (TMA) complications for at least 12 weeks. In aHUS clinical trials, 18 patients (5 in the prospective studies) discontinued Soliris treatment. TMA complications occurred following a missed dose in 5 patients, and Soliris was reinitiated in 4 of these 5 patients.

Clinical signs and symptoms of TMA include changes in mental status, seizures, angina, dyspnea, or thrombosis. In addition, the following changes in laboratory parameters may identify a TMA complication: occurrence of 2, or repeated measurement of any one of the following: a decrease in platelet count by 25% or more compared to baseline or the peak platelet count during Soliris treatment; an increase in serum creatinine by 25% or more compared to baseline or nadir during Soliris treatment; or, an increase in serum LDH by 25% or more over baseline or nadir during Soliris treatment.

If TMA complications occur after Soliris discontinuation, consider reinstitution of Soliris treatment, plasma therapy [plasmapheresis, plasma exchange, or fresh frozen plasma infusion (PE/PI)], or appropriate organ-specific supportive measures.

Thrombosis Prevention and Management
The effect of withdrawal of anticoagulant therapy during Soliris treatment has not been established. Therefore, treatment with Soliris should not alter anticoagulant management.

Infusion-Related Reactions
Administration of Soliris may result in infusion-related reactions, including anaphylaxis or other hypersensitivity reactions. Interrupt Soliris infusion and institute appropriate supportive measures if signs of cardiovascular instability or respiratory compromise occur.

Adverse Reactions
The most frequently reported adverse reactions in the PNH randomized trial (≥10% overall and greater than placebo) are: headache, nasopharyngitis, back pain, and nausea.

The most frequently reported adverse reactions in aHUS single arm prospective trials (≥20%) are: headache, diarrhea, hypertension, upper respiratory infection, abdominal pain, vomiting, nasopharyngitis, anemia, cough, peripheral edema, nausea, urinary tract infections, pyrexia.

Please see accompanying full prescribing information for Soliris, including Boxed WARNING regarding serious meningococcal infections.

Notes

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CALQUENCE

CALQUENCE (acalabrutinib) is a next-generation, selective inhibitor of Bruton's tyrosine kinase (BTK). CALQUENCE binds covalently to BTK, thereby inhibiting its activity.[18,19] In B cells, BTK signaling results in activation of pathways necessary for B-cell proliferation, trafficking, chemotaxis and adhesion.[18]

CALQUENCE is available for prescribing in capsule and tablet formulations in the US. CALQUENCE tablets and capsules are 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.[18,20] Capsules have restrictions in relation to use with gastric acid-reducing agents. The tablets are not licensed in the European Union.

CALQUENCE capsules are approved for CLL in the EU and many other countries worldwide and approved in Japan for relapsed or refractory CLL and SLL. A Phase I trial is currently underway in Japan for the treatment of front-line CLL.

In the US and several other countries, CALQUENCE capsules are also approved for the treatment of adult patients with MCL who have received at least one prior therapy. The US MCL 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 not currently approved for the treatment of MCL in Europe or Japan.

As part of an extensive clinical development program, AstraZeneca and Acerta Pharma are 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, follicular lymphoma and marginal zone lymphoma.

ULTOMIRIS

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 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.

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

SOLIRIS

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 and Japan for the treatment of PNH, aHUS, certain adults with gMG and certain adults with NMOSD.

SOLIRIS is not indicated for the treatment of patients with STEC-HUS.

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.

About Alexion, AstraZeneca Rare Disease

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 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.

About AstraZeneca

AstraZeneca 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. For more information, please visit www.astrazeneca-us.com and follow us on Twitter @AstraZenecaUS.

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