Alexion Receives Positive CHMP Opinion for ULTOMIRIS® (ravulizumab) in Adults with Paroxysmal Nocturnal Hemoglobinuria (PNH)

April 26, 2019

- Final European Commission decision anticipated in June 2019 -

- ULTOMIRIS has the potential to become the new standard of care for both complement inhibitor-naïve patients and patients switching from SOLIRIS® (eculizumab) -

BOSTON & ZURICH--(BUSINESS WIRE)--Apr. 26, 2019-- Alexion Pharmaceuticals, Inc. (NASDAQ:ALXN) today announced that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion, recommending marketing authorization for ULTOMIRIS® (ravulizumab), the first and only long-acting C5 complement inhibitor administered every eight weeks. The recommended indication is for the treatment of adult patients with paroxysmal nocturnal haemoglobinuria (PNH) with haemolysis with clinical symptoms indicative of high disease activity,[1] and also for adult patients who are clinically stable[2] after having been treated with SOLIRIS® (eculizumab) for at least the past six months. PNH is a severe, complement-mediated ultra-rare disease that can cause a wide range of debilitating symptoms and complications, including thrombosis, which can occur throughout the body and result in organ damage and premature death.[3,4,5,6,7,8,9,10]

"This critical milestone brings us one step closer to our goal of bringing ULTOMIRIS to patients with PNH in the EU," said John Orloff, M.D., Executive Vice President and Head of Research & Development at Alexion. "Immediate and complete C5 inhibition sustained for eight weeks can provide meaningful benefits for patients and their families. ULTOMIRIS has the potential to become the new standard of care for patients with PNH based on the totality of our Phase 3 data and the reduction from 26 infusions per year with SOLIRIS to only six or seven for ULTOMIRIS."

The CHMP opinion is based on comprehensive results from two Phase 3 studies, which represent the largest Phase 3 program ever conducted in PNH.[11,12] In these studies, which included more than 440 patients who had either never been treated with a complement inhibitor before,[11] or who had been stable on SOLIRIS,[12] the efficacy of ULTOMIRIS administered every eight weeks was non-inferior to the efficacy of SOLIRIS administered every two weeks on all 11 endpoints. The safety profile of ULTOMIRIS was similar to that of SOLIRIS. Additional data showed that ULTOMIRIS provided immediate and complete C5 inhibition that was sustained for eight weeks,[13] and that ULTOMIRIS eliminated breakthrough hemolysis associated with incomplete C5 inhibition.[14] The entire clinical development program for ULTOMIRIS in PNH to date represents more than 750 patient years of experience.

The European Commission will review the CHMP recommendation and typically delivers its final decision within two months. The U.S. Food and Drug Administration (FDA) approved ULTOMIRIS (ravulizumab-cwvz) for adult patients with PNH on December 21, 2018. Regulatory authorities in Japan are reviewing Alexion's application for the approval of ULTOMIRIS as a treatment for patients with PNH.

About Paroxysmal Nocturnal Hemoglobinuria (PNH)
Paroxysmal nocturnal hemoglobinuria (PNH) is a chronic, progressive, debilitating and life-threatening ultra-rare blood disorder characterized by hemolysis (destruction of red blood cells) that is mediated by an uncontrolled activation of the complement system, a component of the body's immune system.[3,4,15] PNH can strike men and women of all races, backgrounds and ages without warning, with an average age of onset in the early 30s.[3,16] PNH often goes unrecognized, with delays in diagnosis ranging from one to more than five years.[17] Patients with PNH may experience a wide range of signs and symptoms, such as fatigue, difficulty swallowing, shortness of breath, abdominal pain, erectile dysfunction, dark-colored urine and anemia.[5,6,7,8,9,10,15] The most devastating consequence of chronic hemolysis is thrombosis, which can occur in blood vessels throughout the body, damage vital organs and cause premature death.[18] The first thrombotic event can be fatal.[3,16,19] Despite historical supportive care, including transfusion and anticoagulation management, 20 to 35 percent of patients with PNH die within five to 10 years of diagnosis.[20,21] Patients with certain types of hemolytic anemia, bone marrow disorders and unexplained venous or arterial thrombosis are at increased risk of PNH.[15,22,23,24,25,26]

About ULTOMIRIS®
ULTOMIRIS (ravulizumab-cwvz), the first and only long-acting C5 inhibitor administered every eight weeks, is approved in the U.S. as a treatment for adults with paroxysmal nocturnal hemoglobinuria (PNH). ULTOMIRIS works by inhibiting the C5 protein in the terminal complement cascade, a part of the body's immune system. The terminal complement cascade, when activated in an uncontrolled manner, plays a role in severe ultra-rare disorders like PNH, atypical hemolytic uremic syndrome (aHUS), anti-acetylcholine receptor (AchR) antibody-positive myasthenia gravis (MG) and anti-aquaporin-4 (AQP4) auto-antibody-positive neuromyelitis optica spectrum disorder (NMOSD). Regulatory authorities in the European Union (EU) and Japan are reviewing applications for the approval of ULTOMIRIS as a treatment for adult patients and patients with PNH, respectively. In Phase 3 clinical studies in complement inhibitor-naïve patients with PNH[11] and patients with PNH who had been stable on SOLIRIS® (eculizumab),[12] intravenous treatment with ULTOMIRIS every eight weeks demonstrated non-inferiority to intravenous treatment with SOLIRIS every two weeks on all 11 endpoints.

The Phase 3 study of ULTOMIRIS, administered intravenously every eight weeks in adult patients with aHUS, met its primary objective. Alexion has submitted a supplemental Biologics License Application (sBLA) to the U.S. Food and Drug Administration (FDA) for approval of ULTOMIRIS as a treatment for patients with aHUS and plans to submit similar applications in the EU and Japan later in 2019. ULTOMIRIS is also currently being evaluated in a Phase 3 clinical study in children and adolescents with aHUS, administered intravenously every eight weeks. Alexion has initiated a Phase 3 study of ULTOMIRIS, intravenously administered every eight weeks, as a potential treatment for patients with generalized MG (gMG), and is planning to initiate a Phase 3 in patients with NMOSD. In addition, Alexion has initiated Phase 3 studies of ULTOMIRIS delivered subcutaneously once

per week as a potential treatment for patients with PNH, aHUS and gMG.

ULTOMIRIS has received Orphan Drug Designation (ODD) for the treatment of patients with PNH in the U.S., EU and Japan and for the subcutaneous treatment of patients with aHUS in the U.S.

U.S. Indication of ULTOMIRIS® (ravulizumab-cwvz)
ULTOMIRIS is a prescription medicine called a monoclonal antibody. ULTOMIRIS is used to treat adults with a disease called paroxysmal nocturnal hemoglobinuria (PNH). It is not known if ULTOMIRIS is safe and effective in children.

U.S. Important Safety Information for ULTOMIRIS® (ravulizumab-cwvz)
ULTOMIRIS is a medicine that affects the immune system. ULTOMIRIS can lower the ability of the immune system to fight infections. ULTOMIRIS increases the chance of getting serious and life-threatening meningococcal infections. Meningococcal infections may quickly become life-threatening and cause death if not recognized and treated early.

Meningococcal vaccines must be received at least 2 weeks before the first dose of ULTOMIRIS if one has not already had this vaccine. If one's doctor decided that urgent treatment with ULTOMIRIS is needed, meningococcal vaccination should be administered as soon as possible. If one has not been vaccinated and ULTOMIRIS therapy must be initiated immediately, 2 weeks of antibiotics should also be administered with the vaccinations. If one had a meningococcal vaccine in the past, additional vaccination might be needed before starting ULTOMIRIS. Call one's doctor or get emergency medical care right away if any of these signs and symptoms of a meningococcal infection occur: headache with nausea or vomiting, headache with a stiff neck or stiff back, fever and a rash, muscle aches with flu-like symptoms, headache and fever, fever, confusion, and eyes sensitive to light.

ULTOMIRIS is only available through a program called the ULTOMIRIS REMS.

ULTOMIRIS may also increase the risk of other types of serious infections. People who take ULTOMIRIS may have an increased risk of getting infections caused by *Streptococcus pneumoniae* and *Haemophilus influenzae*. Certain people may also have an increased risk of gonorrhea infection. To find out if one is at risk for gonorrhea infection, about gonorrhea prevention, and regular testing, talk to the healthcare provider. Call the healthcare provider right away if one has any new signs or symptoms of infection.

Before one receives ULTOMIRIS, tell the doctor about all of the medical conditions, including if one: has an infection or fever, is pregnant or plans to become pregnant, and is breastfeeding or plans to breastfeed. It is not known if ULTOMIRIS will harm an unborn baby. It is not known if ULTOMIRIS passes into the breast milk. One should not breast feed during treatment and for 8 months after one's final dose of ULTOMIRIS.

Tell the doctor about all the medicines one takes, including prescription and over-the-counter medicines, vitamins, and herbal supplements. ULTOMIRIS and other medicines can affect each other causing side effects. Know the medications one takes and the vaccines one receives. Keep a list of them to show the doctor and pharmacist when one gets a new medicine.

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

ULTOMIRIS can cause serious side effects including infusion reactions. Infusion reactions may happen during one's ULTOMIRIS infusion. Symptoms of an infusion reaction with ULTOMIRIS may include lower back pain, pain with the infusion, or feeling faint. Tell the doctor or nurse right away if these symptoms develop, or any other symptoms during the ULTOMIRIS infusion that may mean one is having a serious infusion reaction, including: chest pain, trouble breathing or shortness of breath, swelling of the face, tongue, or throat, and feel faint or pass out. One's doctor will treat the symptoms as needed. The most common side effects of ULTOMIRIS are upper respiratory infection and headache.

For more information, please see the full U.S. Prescribing Information and Medication Guide for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening meningococcal infections/sepsis, also available at: www.ultomiris.com.

About SOLIRIS® (eculizumab)
SOLIRIS® is a first-in-class complement inhibitor that works by inhibiting the C5 protein in the terminal part of the complement cascade, a part of the immune system. The terminal complement cascade, when activated in an uncontrolled manner, plays a role in severe rare and ultra-rare disorders like paroxysmal nocturnal hemoglobinuria (PNH), atypical hemolytic uremic syndrome (aHUS), and anti-acetylcholine receptor (AchR) antibody-positive myasthenia gravis (MG). SOLIRIS is approved in the U.S., EU, Japan and other countries as a treatment for adult patients with PNH and for adults and children with aHUS. SOLIRIS is not indicated for the treatment of patients with Shiga-toxin E. coli-related hemolytic uremic syndrome (STEC-HUS). In the U.S., SOLIRIS is also approved for the treatment of adult patients with generalized MG (gMG) who are anti-AchR antibody-positive, in the EU as the first and only treatment of refractory gMG in adults who are anti-AchR antibody-positive and in Japan for the treatment of patients with gMG who are AChR antibody-positive and whose symptoms are difficult to control with high-dose intravenous immunoglobulin (IVIG) therapy or plasmapheresis (PLEX).

SOLIRIS has received Orphan Drug Designation (ODD) for the treatment of patients with PNH in the U.S., EU, Japan and many other countries, for the treatment of patients with aHUS in the U.S., EU, and many other countries, for the treatment of patients with MG in the U.S. and EU and for the treatment of patients with refractory gMG in Japan. Alexion and SOLIRIS have received some of the pharmaceutical industry's highest honors for the medical innovation in complement inhibition: the Prix Galien USA (2008, Best Biotechnology Product) and France (2009, Rare Disease Treatment).

U.S. Indication of SOLIRIS® (eculizumab)
SOLIRIS is a prescription medicine called a monoclonal antibody. SOLIRIS is used to treat patients with a disease called Paroxysmal Nocturnal Hemoglobinuria (PNH). It is not known if SOLIRIS is safe and effective in children with PNH.

U.S. Important Safety Information for SOLIRIS® (eculizumab)
SOLIRIS is a medicine that affects the immune system. SOLIRIS can lower the ability of the immune system to fight infections. SOLIRIS increases the chance of getting serious and life-threatening meningococcal infections. Meningococcal infections may quickly become life-threatening and cause death if not recognized and treated early.

Meningococcal vaccines must be received at least 2 weeks before the first dose of SOLIRIS if one has not already had this vaccine. If one's doctor decided that urgent treatment with SOLIRIS is needed, meningococcal vaccination should be administered as soon as possible. If one has not been vaccinated and SOLIRIS therapy must be initiated immediately, 2 weeks of antibiotics should also be administered with the vaccinations. If one had a meningococcal vaccine in the past, additional vaccination might be needed before starting SOLIRIS. Call one's doctor or get emergency medical care right away if any of these signs and symptoms of a meningococcal infection occur: 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.

SOLIRIS is only available through a program called the SOLIRIS REMS.

SOLIRIS may also increase the risk of other types of serious infections. If one's child is treated with SOLIRIS, make sure that the child receives vaccinations against *Streptococcus pneumoniae* and *Haemophilus influenzae* type b (Hib). Certain people may be at risk of serious infections with gonorrhea. Talk to the doctor about whether one is at risk for gonorrhea infection, about gonorrhea prevention, and regular testing. Certain fungal infections (Aspergillus) may also happen if one takes SOLIRIS and has a weak immune system or a low white blood cell count.

Before one receives SOLIRIS, tell the doctor about all of the medical conditions, including if one: has an infection or fever, is pregnant or plans to become pregnant, and is breastfeeding or plans to breastfeed. It is not known if SOLIRIS will harm an unborn baby. It is not known if SOLIRIS passes into the breast milk.

Tell the doctor about all the medicines one takes, including prescription and over-the-counter medicines, vitamins, and herbal supplements. SOLIRIS and other medicines can affect each other causing side effects.

It is important that one: has all recommended vaccinations before starting SOLIRIS, receives 2 weeks of antibiotics if one immediately starts SOLIRIS, and stays up-to-date with all recommended vaccinations during treatment with SOLIRIS. Know the medications one takes and the vaccines one receives. Keep a list of them to show the doctor and pharmacist when one gets a new medicine.

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

SOLIRIS can cause serious side effects including serious allergic reactions. Serious allergic reactions can happen during one's SOLIRIS infusion. Tell the doctor or nurse right away if one gets any of these symptoms during the SOLIRIS infusion: chest pain, trouble breathing or shortness of breath, swelling of the face, tongue, or throat, and feeling faint or pass out. If one has an allergic reaction to SOLIRIS, the 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 the nose or throat (nasopharyngitis), back pain, and nausea.

For more information, please see the accompanying full U.S. Prescribing Information and Medication Guide for SOLIRIS, including Boxed WARNING regarding serious and life-threatening meningococcal infections, also available at: www.soliris.net.

About Alexion
Alexion is a global biopharmaceutical company focused on serving patients and families affected by rare diseases through the discovery, development and commercialization of life-changing therapies. As the global leader in complement biology and inhibition for more than 20 years, Alexion has developed and commercializes two approved complement inhibitors to treat patients with paroxysmal nocturnal hemoglobinuria (PNH) as well as the first and only approved complement inhibitor to treat atypical hemolytic uremic syndrome (aHUS) and anti-acetylcholine receptor (AchR) antibody-positive generalized myasthenia gravis (gMG), and is also developing it for patients with neuromyelitis optica spectrum disorder (NMOSD). Alexion also has two highly innovative enzyme replacement therapies for patients with life-threatening and ultra-rare metabolic disorders, hypophosphatasia (HPP) and lysosomal acid lipase deficiency (LAL-D). In addition, the company is developing several mid-to-late-stage therapies, including a second complement inhibitor, a copper-binding agent for Wilson disease and an anti-neonatal Fc receptor (FcRn) antibody for rare Immunoglobulin G (IgG)-mediated diseases as well as several early-stage therapies, including one for light chain (AL) amyloidosis and a second anti-FcRn therapy. Alexion focuses its research efforts on novel molecules and targets in the complement cascade and its development efforts on the core therapeutic areas of hematology, nephrology, neurology, and metabolic disorders. Alexion has been named to the Forbes list of the World's Most Innovative Companies seven years in a row and is headquartered in Boston, Massachusetts' Innovation District. The company also has offices around the globe and serves patients in more than 50 countries. This press release and further information about Alexion can be found at: www.alexion.com.

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Forward-Looking Statement
This press release contains forward-looking statements that involve risks and uncertainties relating to future events and the future performance of Alexion, including statements related to: the final European Commission decision on the potential approval of ULTOMIRIS® in adults with PNH is anticipated in June 2019; the Company's goal is to bringing ULTOMIRIS to patients with PNH in the EU; ULTOMIRIS has the potential to become the new standard of care for patients with PNH; the expected timing of the final decision of the European Commission with respect to pharmaceutical product approval including ULTOMIRIS for PNH; Alexion's future plans for submitting supplemental Biologics License Application and similar applications to the applicable regulatory authorities for ULTOMIRIS as a therapy for certain indications, including the anticipated timing of certain filings in the US, EU and Japan later in 2019; ULTOMIRIS is a potential treatment for patients with generalized MG (gMG); the Company is planning to initiate a Phase 3 clinical trial in patients with NMOSD; ULTOMIRIS can provide meaningful benefits for patients with PNH and their families; the anticipated timing of the review and decision of regulatory agencies with respect to the potential approval of ULTOMIRIS as a treatment for PNH in certain jurisdictions; future plans for the evaluation and clinical trials of ULTOMIRIS in additional indications and patient populations; and the potential medical benefits of ULTOMIRIS for the treatment of PNH and other diseases. Forward-looking statements are subject to factors that may cause Alexion's results and plans to differ materially from those expected by these forward looking statements, including for example: our inability to facilitate the timely conversion of PNH patients (and any future indications) from Soliris to ULTOMIRIS; payer, physician and patient acceptance of ULTOMIRIS as an alternative to Soliris; ULTOMIRIS does not gain market acceptance and/or does not become the standard of care for patients with PNH and/or is not recognized by patients and physicians as the standard of care for patients with PNH; the benefits (including safety and efficacy) of ULTOMIRIS evidenced in clinical trials are not witnessed in a broader patient population; any potential post-approval restrictions that the FDA or any other regulatory agency may impose on ULTOMIRIS; ULTOMIRIS does not gain regulatory approval from the EMA or Japanese regulatory authority as a treatment for PNH; ULTOMIRIS does not gain approval from regulatory agencies as a treatment for indications beyond PNH; delays (expected or

unexpected) in the time it takes regulatory agencies to review and make determinations on applications for the marketing approval of our products (including ULTOMIRIS as a treatment for PNH); inability to timely submit (or failure to submit) future applications for regulatory approval for our products and product candidates; inability to timely initiate (or failure to initiate) future clinical trials due to safety issues, IRB decisions, expense or unfavorable results from earlier trials (among others); our dependence on sales from our principal product (SOLIRIS); future competition from biosimilars and other products; decisions of regulatory authorities regarding the adequacy of our research, marketing approval or material limitations on the marketing of our products; delays or failure of product candidates (including ULTOMIRIS) to obtain regulatory approval; delays or the inability to launch product candidates due to regulatory restrictions, anticipated expense or other matters; interruptions or failures in the manufacture and supply of our products and our product candidates; failure to satisfactorily address matters raised by the FDA and other regulatory agencies; results in early stage clinical trials may not be indicative of full results or results from later stage or larger clinical trials (or broader patient populations) and do not ensure regulatory approval; the possibility that results of clinical trials are not predictive of safety and efficacy and potency of our products (or we fail to adequately operate or manage our clinical trials) which could cause us to halt trials, delay or prevent us from making regulatory approval filings or result in denial of approval of our product candidates; future product improvements may not be realized due to expense or feasibility; uncertainty of long-term success in developing, licensing or acquiring other product candidates or additional indications for existing products; the possibility that current rates of adoption of SOLIRIS in PNH, aHUS, gMG or other diseases (and ULTOMIRIS in PNH in the US) are not sustained; the adequacy of our pharmacovigilance and drug safety reporting processes; failure to protect and enforce our data, intellectual property and proprietary rights and the risks and uncertainties relating to intellectual property claims and challenges against us (including intellectual property lawsuits relating to ULTOMIRIS brought by third parties against Alexion and inter partes review petitions submitted by third parties); the risk that third party payers (including governmental agencies) will not reimburse or continue to reimburse for the use of our products at acceptable rates or at all; failure to realize the benefits and potential of investments, collaborations, licenses and acquisitions; delay of collection or reduction in reimbursement due to adverse economic conditions or changes in government and private insurer regulations and approaches to reimbursement; uncertainties surrounding legal proceedings (including intellectual property suits initiated against Alexion and our products), company investigations and government investigations, including investigations of Alexion by the U.S. Securities and Exchange Commission (SEC) and U.S. Department of Justice; the risk that estimates regarding the number of patients with PNH, aHUS, gMG, NMOSD, HPP and LAL-D and other future indications we are pursuing are inaccurate; the risks of changing foreign exchange rates; risks relating to the potential effects of the Company's restructuring; risks related to the acquisition of Syntimmune and other companies and co-development efforts; and a variety of other risks set forth from time to time in Alexion's filings with the SEC, including but not limited to the risks discussed in Alexion's Quarterly Report on Form 10-Q for the period ended March 31, 2019 and in our other filings with the SEC. Alexion disclaims any obligation to update any of these forward-looking statements to reflect events or circumstances after the date hereof, except when a duty arises under law.

References

1 With high disease activity defined as lactate dehydrogenase (LDH) levels (a direct marker of haemolysis) ≥ 1.5 × upper limit of normal (ULN) at screening along with the presence of one or more of the following PNH-related signs or symptoms within three months of screening: fatigue, haemoglobinuria, abdominal pain, shortness of breath (dyspnoea), anaemia (haemoglobin < 10 g/dL), history of a major adverse vascular event (including thrombosis), dysphagia, or erectile dysfunction, or history of packed red blood cell transfusion due to PNH.

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