Healthcare Provider Enrollment Form

ONESOURCE™ TREATMENT SUPPORT | OneSource Safety Support Program

Dear Soliris® (eculizumab) Prescriber,

Alexion, the maker of Soliris, would like to notify you of a Risk Evaluation and Mitigation Strategy (REMS) called the OneSource Safety Support Program (OSSP) to provide important safety information about Soliris.

To get started in the Program, please complete the Prescriber Enrollment Form on the reverse side. The completed Prescriber Enrollment Form can be faxed to the Soliris OneSource Safety Support Program (OSSP) at 1.877.580.2596 (ALXN); scanned and e-mailed to OSSP@alexion.com; or mailed to Alexion Pharmaceuticals, Inc., Attn: OneSource Safety Support Program; 100 College Street, New Haven, CT 06510. Enrollment can also be completed online at www.solirisrems.com.

I have received the Soliris educational materials provided through the Soliris OneSource Safety Support Program and I have reviewed information about:

- The need for the patient to receive meningococcal vaccination at least 2 weeks prior to beginning Soliris (eculizumab), unless the risk of delaying Soliris therapy outweighs the risk of developing meningococcal infection
- The risks of developing meningococcal infection while receiving Soliris (eculizumab)

I agree to:

- Review the product labeling and educational materials, and comply with the safety instructions for use, including ensuring meningococcal vaccination status
- Counsel patients (or caregivers, or legal guardians) and provide educational materials to the patient (or caregivers, or legal guardians), including the Soliris Patient Safety Information Card, and the Soliris Medication Guide
- Intend to promptly report cases of meningococcal infection, including the patient's clinical outcomes, by contacting Alexion Pharmaceuticals, Inc., (OneSource Safety Support Program) at 1.844.259.6783 or reporting the information to the FDA MedWatch Reporting System by phone at 1.800.FDA.1088 (1.800.332.1088) or by mail using Form 3500 at www.fda.gov/medwatch
- Revaccinate patients in accordance with the Advisory Committee on Immunization Practices (ACIP) recommendations for the duration of Soliris therapy

WARNING: SERIOUS MENINGOCOCCAL INFECTIONS

Life-threatening and fatal meningococcal infections have occurred in patients treated with Soliris. 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 Soliris, unless the risks of delaying Soliris therapy outweigh the risks of developing a meningococcal infection. [see *Warnings and Precautions (5.1)* for additional guidance on the management of the risk of meningococcal infection.]
- 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.

Please complete enrollment form on the reverse side of this letter.

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INDICATIONS AND USAGE

Soliris is a complement inhibitor indicated for:

- The treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis.
- The treatment of patients with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy.
- The treatment of patients with generalized Myasthenia Gravis (gMG) who are anti-Acetylcholine Receptor (AchR) antibody positive.

Limitation of Use

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

CONTRAINDICATIONS

Soliris is contraindicated in:

- Patients with unresolved *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

- Discontinue Soliris in patients who are being treated for serious meningococcal infections.
- Use caution when administering Soliris to patients with any other systemic infection.

ADVERSE REACTIONS

- The most frequently reported adverse reactions in the PNH randomized trials (≥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% combined per patient incidence) are: headache, diarrhea, hypertension, upper respiratory infection, abdominal pain, vomiting, nasopharyngitis, anemia, cough, peripheral edema, nausea, urinary tract infections, and pyrexia.
- The most frequently reported adverse reaction in the gMG placebo-controlled clinical trial (≥10% and greater than placebo) is: musculoskeletal pain.

Please see full prescribing information for Soliris (eculizumab), including boxed WARNING regarding serious meningococcal infection.

I acknowledge that I have read the above information and agree to comply with the conditions listed when treating a patient with Soliris.

Name (printed): _____

Signature: _____ Date: _____

Title: _____

Office Address: _____ E-mail: _____

City: _____ State: _____ ZIP: _____ Country: _____

Phone Number: _____ Fax Number: _____