ONESOURCE®
Personalized Patient Support from Alexion

Atypical Hemolytic Uremic Syndrome (aHUS)
ENROLMENT FORM

TELEPHONE: 1-888-765-4747 FAX: 1-877-301-2596 EMAIL: OSPinfo@innomar-strategies.com

ULTOMIRIS® (ravulizumab) injection for intravenous use

PATIENT INFORMATION

Patient's name: First name Last name Date of birth: (DD/MM/YYYY)

Gender: ☐ F ☐ M ☐ Other Patient's weight: kg

Home phone: Leave messages: ☐ Y ☐ N Email:

Other phone: Leave messages: ☐ Y ☐ N Consent to receive emails: ☐ Y ☐ N

Health card #: Patient currently hospitalized: ☐ Y ☐ N Consent to contact patient in hospital: ☐ Y ☐ N

Alternate contact's name: Telephone: Email:

PHYSICIAN INFORMATION

Physician's name: Email: Postal code:

Key contact/Admin: Email: Telephone: Fax:

Nurse: Email: Telephone: Fax:

Additional comments:

TREATMENT PLAN

Please choose ONE of the following locations for treatment start:

☐ Infusion clinic ☐ Home ☐ Urgent access (Hospitalized Patient) ☐ Other: _____

PRESCRIPTION

ULTOMIRIS® (ravulizumab)
(Refer to Product Monograph for complete prescribing information)

For patients switching from SOLIRIS® to ULTOMIRIS®, the loading dose of ULTOMIRIS® should be administered at the time of the next scheduled SOLIRIS® infusion, and then ULTOMIRIS® maintenance doses are administered once every 8 weeks for patients ≥ 20kg, starting 2 weeks after loading dose administration.

☐ atypical Hemolytic Uremic Syndrome (aHUS)

≥5 to <10kg:
☐ 600mg loading dose X 1 dose, 300mg 2 weeks after loading dose, and every 4 weeks thereafter

≥10 to <20kg:
☐ 600mg loading dose X 1 dose, 600mg 2 weeks after loading dose, and every 4 weeks thereafter

≥20 to <30kg:
☐ 900mg loading dose X 1 dose, 2100mg 2 weeks after loading dose, and every 8 weeks thereafter

≥30 to <40kg:
☐ 1200mg loading dose X 1 dose, 2700mg 2 weeks after loading dose, and every 8 weeks thereafter

≥40 to <60kg:
☐ 2400mg loading dose X 1 dose, 3000mg 2 weeks after loading dose, and every 8 weeks thereafter

≥60 to <100kg:
☐ 2700mg loading dose X 1 dose, 3300mg 2 weeks after loading dose, and every 8 weeks thereafter

≥100kg:
☐ 3000mg loading dose X 1 dose, 3600mg 2 weeks after loading dose, and every 8 weeks thereafter

☐ Other Condition: _____

REPEATS ☐ 12 months ☐ Other: _____

REQUIRED PRE-TREATMENT VACCINATION

Due to its mechanism of action, the use of ULTOMIRIS® increases the patient's susceptibility to meningococcal infection/sepsis (*Neisseria meningitidis*). To reduce this risk of infection, all patients must be vaccinated against meningococcal infections prior to, or at the time of, initiating ULTOMIRIS®. Patients who initiate ULTOMIRIS® treatment less than 2 weeks after receiving a meningococcal vaccine must receive treatment with appropriate prophylactic antibiotics until 2 weeks after vaccination. Vaccination may not be sufficient to prevent meningococcal infection. Consideration should be given to official guidance on the appropriate use of antibacterial agents.

Patients below the age of 18 years old must be vaccinated against *Haemophilus influenzae* and pneumococcal infections and need to adhere strictly to the National Advisory Committee on Immunization (NACI) and the CIG (Canadian Immunization Guide) vaccination recommendations for their age group.

WARNING

Patients must be vaccinated against meningococcal infections prior to, or at the time of, initiating ULTOMIRIS®, unless the risks of delaying ULTOMIRIS® therapy outweigh the risks of developing a meningococcal infection. Comply with the most current National Advisory Committee on Immunization (NACI) recommendations for meningococcal vaccination in patients with complement deficiencies.

MENINGOCOCCAL VACCINATION / PROPHYLACTIC ANTIBIOTICS STATUS

Please select which of the following applies to your patient:

☐ The patient is fully vaccinated against all available meningococcal infections serotypes of *Neisseria meningitidis* according to the product monograph for ULTOMIRIS®, National Advisory Committee on Immunization (NACI), and Canadian Immunization Guide (CIG) guidelines.
Program to initiate treatment: ☐ immediately or ☐ after this date:_____

☐ The patient is partially vaccinated. Patients who initiate treatment less than 2 weeks after receiving a meningococcal vaccine will receive treatment with appropriate prophylactic antibiotics until 2 weeks after first vaccination. The OneSource™ program will follow-up with the physician for clarification.

☐ The patient has not received any meningococcal vaccinations. OneSource™ program to proceed with administering vaccines. Patients will be eligible to start treatment 2 weeks post first vaccine of both serotypes. Please complete the prescription below.

PRESCRIPTION

Meningococcal vaccine
(Refer to Product Monograph and NACI recommendation for high-risk individuals for complete prescribing information)

Administer as directed:

Men-C-ACYW:
☐ Menveo® or ☐ Menactra® or ☐ Nimenrix® # of Doses _____ given _____ weeks apart

and

Men-B:
☐ Bexsero® or ☐ Trumenba® # of Doses _____ given _____ weeks apart

NACI recommendation for high-risk individuals: Menveo®, Menactra®, Nimenrix®, 2 doses, given 8 weeks apart; Bexsero®, 2 doses, given at least 4 weeks apart; Trumenba®, 3 doses, given 4 weeks apart, with another dose 4 months after dose two and at least 6 months after dose one. Booster: Meningococcal booster vaccination is recommended for individuals who have previously received the initial meningococcal vaccination. The specific timing of the booster vaccine should follow the latest NACI and CIG guidelines for individuals with acquired complement deficiency.

PRESCRIBING PHYSICIAN AUTHORIZATION

I certify that I am the patient's prescribing physician and confirm that the patient has been prescribed the Product as per the Canadian product monograph. This Product has been prescribed for this patient based on my independent medical judgement and the patient's informed consent.

I agree to be contacted by Innomar Strategies Inc., or the current administrator of the Program, about the patient, the Product, the OneSource™ Program (the "Program") and any adverse events or Product complaints. I consent to the use of my prescribing information for the purpose of administering, monitoring, and assessing the Program. My personal information will be collected, stored, and processed for use as described in this authorization form. Questions regarding privacy and compliance may be addressed to the Alexion Canada Privacy Officer via email at privacy@alexion.com.

I authorize the Program Administrator in the context of the Program to be my designated agent to forward the prescription by fax or other mode of delivery to the pharmacy chosen by the above-named patient. This prescription represents the original prescription drug order.

I agree to keep all confidential information provided to me about the Program in strict confidence and shall not, without Alexion's prior written consent, disclose any confidential information to any third party.

Physician Signature: _____ Date (DD/MM/YYYY): _____

PATIENT AUTHORIZATION AND CONSENT

I have read and understand the Patient Authorization and Consent on the reverse and agree to the collection, use, and disclosure of my personal and health information in accordance with those terms.

Patient Signature: _____

Date (DD/MM/YYYY): _____

OR

Patient has given verbal consent to proceed with enrolment at this time and the Program Administrator will provide the Patient Authorization and Consent Information, at a later date.

Name of Person Collecting Verbal Consent: _____

Signature: _____

Date verbal consent collected (DD/MM/YYYY): _____

OPTIONAL INFORMATION: Your response to the following check boxes will not impact your ability to access the products and services through this Program.

Do you consent to:

Be connected with Alexion Patient Advocacy, or a third party working on its behalf, for opportunities related to disease awareness campaigns, media interviews, peer mentoring, or patient advocacy.
☐ Y ☐ N

Be contacted by Alexion, or a third party working on its behalf, for purposes of market research, to help improve our support programs, patient and clinician information, or diagnostic testing initiatives.
☐ Y ☐ N

Be contacted by Alexion Medical, or a third party working on its behalf, to understand your interest in participating in a Real-World Data study.
☐ Y ☐ N

Patient Authorization and Consent

The purpose of the OneSource™ Program ("Program") is to provide patients with support including education, reimbursement navigation, and/or services related to the Product. By signing this Authorization and Consent Form, you or your representative agree to all the terms and conditions as further described below.

The Program is being managed by Alexion Pharma Canada and is administered by Innomar Strategies Inc., ("Program Administrator"), an independent third party. Alexion may, at its sole discretion, appoint a new program administrator at any time. By signing this form, you consent to the transfer of your Personal Information, as well as the prescription itself (if applicable), to any future program administrator, if required.

You understand that the Program is not intended to provide medical advice or medical diagnoses. You should always seek the advice of your physician if you have any health concerns. You have discussed the benefits and risks of the Product with your physician and have decided to start treatment. You understand that it is your right to refuse to sign this consent form and if you do not give such consent, you will not be provided with access to the Program.

Alexion reserves the right at any time, without notice, to modify, discontinue, or terminate the Program.

You agree to enroll in the Program and authorize for your information, including contact information and information about your insurance, prescriptions, medical condition, diagnostic test results and other health information from your healthcare providers ("Personal Information") to be collected, used, and disclosed as described in this form. In addition, you consent to the Program Administrator contacting you to provide the Program services.

Personal Information: Collection, Use, and Disclosure

To participate in the Program, you are required to provide your Personal Information to the Program Administrator, and you authorize the Program Administrator to contact your insurer and your Healthcare Providers (HCPs) for additional information.

The Personal Information may include name, address, other contact information, date of birth, diagnoses, medical reports, orders, prescriptions, records, medical histories, findings, prognoses, plans of care and discharge summaries, billing information, insurance claims, utilization review reports, survey responses, and other information you provide in connection with your Program participation. Your Personal Information may be used or disclosed for the following purposes and is required for participating in the program:

Coordination of Care: Between you or your representative, HCP, Distributor (wholesaler, pharmacy, infusion clinic, or home health agency that supplies or dispenses your medical therapy), or Payor (your health insurer or patient assistance program) for the coordination of your medical care, including therapy adherence reminders.

Disease Management/Patient Education: To provide information, training, and case management services to you or your representative.

Reviewing Your Insurance Coverage/Funding Options: To review, verify, and assist you or your representative with your reimbursement navigation. This may include review of your personal financial information to determine if you qualify for financial assistance which may be available under the OneSource™ Program. If you do not qualify for insurance or other coverage to pay for your treatment, your Personal Information and other information may be used to determine if you might qualify in the future for such coverage or to help you identify other sources of payment or financial support.

Billing and Payment: To coordinate the preparation, filing, and processing of health insurance claims, the evaluation of coding (billing) issues, and the resolution or collection of any payment due to HCP, Distributor, Payor, or Alexion for your treatment.

Distribution of Therapy: To coordinate the distribution of the Product to you.

Product Orders: To fulfill Product orders, answer any questions that you or your representative may have, and inform you about other services that may be of interest to you.

Government Agencies: To provide information as required or requested by representatives of government agencies, review boards, and others who watch over the safety of drugs (or operations) of pharmaceutical manufacturers. Alexion has a legal obligation to report adverse drug events to various local and international health authorities and to monitor product complaints. Personal Information provided to the Program may be (i) monitored by Alexion for safety related data in order to ensure compliance with these legal reporting requirements and (ii) reported to local or international health authorities. Alexion may contact you or your physician for additional information to fulfill its reporting obligations.

Your Identifiable Personal Information will be confidentially collected, used, and disclosed by the Program Administrator to provide the Program services, and the administration and monitoring of the Program, and may be shared with:

- Alexion for Program auditing and troubleshooting purposes and to fulfill its legal adverse drug event reporting and complaints handling obligations to Health Canada;
- Public and private insurers for the purpose of investigating drug reimbursement options; and
- HCPs who may share your personal information with your insurers for the purpose of investigating drug reimbursement options.

Transfer and Processing of Personal Information

Your Personal Information may be transferred, including between provinces or outside of Canada, for the purposes of communicating the information to Alexion's parent and affiliated entities, and/or for the purposes of storing and processing the information on behalf of Alexion in relation to the OneSource™ Program. Your Consent serves as explicit consent that your data can be transferred and processed in countries outside Canada, which may not ensure the same level of data protection as provided in Canada, to provide you with the information you requested. The Personal Information will be protected while outside of Canada; however, to the extent required under applicable law, your Personal Information may be accessed by the courts, law enforcement, and national security authorities of that other country. Your Personal Information collected as part of the Program will be protected by reasonable physical, administrative, and technical safeguards to protect it against loss, theft and unauthorized consultation, communication, copying, use, or alteration.

Coded Data and Aggregated Data

Information collected during your participation in the Program by the Program Administrator may be provided to Alexion in a coded format, which may be used by Alexion for internal evaluation purposes, such as determining whether certain aspects of the Program require refinement. Coded information means that information that can personally identify you is replaced by a code. Only the Program Administrator has a key to that code. Alexion may also use your coded data to generate fully de-identifiable aggregated data that does not contain Personal Information (the "Aggregated Data"). The Aggregated Data may be used to improve and refine the OneSource™ Program and to design and implement other patient programs. Alexion, or a third party acting on its behalf, may also use such information for analytics, reporting, and research purposes, including clinical publications, and strategy development and the identification of trends such as product utilization, adherence, or outcomes. Any third parties who receive such Aggregated Data must agree that they will not attempt to make the information personally identifiable, such as by combining it with other databases.

Withdrawing Consent

This Authorization and Consent may be revoked by you at any time. Please note that if you revoke this Authorization and Consent, your ability to receive OneSource™ Program services may be limited. To revoke your consent, update or access your Personal Information, express a privacy-related concern, or inquire about the privacy practices of the OneSource™ Program, you may contact the Alexion Canada Privacy Officer by email at privacy@alexion.com.

ULTOMIRIS® (ravulizumab for injection) Indication

ULTOMIRIS® (ravulizumab for injection) 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). Limitations of Use: ULTOMIRIS® is not indicated for the treatment of patients with Shiga toxin *E. coli* related hemolytic uremic syndrome (STEC-HUS).

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ULTOMIRIS® (ravulizumab) injection for intravenous use