BLA 761032 SILIQ™ (brodalumab)  
Human Interleukin-17 Receptor A (IL-17RA) Antagonist  
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RISK EVALUATION AND MITIGATION STRATEGY (REMS)  

I. GOALS  
The goal of the SILIQ REMS Program is to mitigate the observed risk of suicidal ideation and behavior, including completed suicides, which occurred in subjects treated with SILIQ by:  

• Ensuring that prescribers are educated about the risk of suicidal ideation and behavior observed with SILIQ therapy and the need to counsel patients about this risk.  
• Ensuring that patients are informed about the risk of suicidal ideation and behavior observed with SILIQ therapy and the need to seek medical attention for manifestations of suicidal thoughts and behavior, new onset or worsening depression, anxiety, or other mood changes.  

II. ELEMENTS  

A. Elements to Assure Safe Use  

1. Healthcare providers who prescribe SILIQ must be certified.  
   a. To become certified to prescribe SILIQ, prescribers must:  
      i. Review the Prescribing Information (PI) for SILIQ.  
      ii. Enroll in the SILIQ REMS Program by completing the SILIQ REMS Program Prescriber Enrollment Form.  
   b. As a condition of certification, prescribers must:  
      i. Enroll each patient in the SILIQ REMS Program by performing the following:  
         1) Prior to providing the first prescription, counsel the patient that suicidal ideation and behavior (SIB), including completed suicides, have occurred in patients treated with SILIQ by informing the patient of the following key safety information:  
            a) Suicidal ideation and behavior (SIB) events and symptoms may occur at any time during treatment with SILIQ.  
            b) To be aware of symptoms of suicidal ideation and behavior (SIB) events and steps to take if SIB symptoms occur.
2) Complete the *SILIQ REMS Program Patient-Prescriber Agreement Form* for each patient. Submit the completed form to the SILIQ REMS Program and store a copy in the patient’s records.

3) Provide the patient with the *SILIQ REMS Program Patient Wallet Card.*
   a) Understand that patients with new or worsening symptoms of depression or suicidality should be referred to a mental health professional, as appropriate.
   b) Inform SILIQ REMS Program if an enrolled patient has discontinued therapy or is no longer under your care.

c. Bausch Health US, LLC. (Bausch Health) must:
   i. Ensure that prescribers who prescribe SILIQ are certified, in accordance with the requirements described above.
   ii. Provide all the following mechanisms for prescribers to complete the certification process for the SILIQ REMS Program: online, by email, and by fax.
   iii. Ensure that prescribers are notified when they have been certified by the SILIQ REMS Program.
   iv. Maintain a validated, secure database of prescribers who are certified to prescribe SILIQ in the SILIQ REMS Program.
   v. Ensure that prescribers meet the REMS requirements and de-certify prescribers who do not maintain compliance with REMS requirements.
   vi. Ensure that certified prescribers are provided access to the database of certified pharmacies and enrolled patients.
   vii. Provide the *SILIQ REMS Program Prescriber Enrollment Form, SILIQ REMS Program Patient-Prescriber Agreement Form, SILIQ REMS Program Patient Wallet Card,* and the Prescribing Information to prescribers who (1) attempt to prescribe SILIQ and are not yet certified, or (2) inquire about how to become certified.

The following materials are part of the REMS and are appended:
   - *SILIQ REMS Program Prescriber Enrollment Form*
   - *SILIQ REMS Program Patient-Prescriber Agreement Form*
   - *SILIQ REMS Program Patient Wallet Card*

2. **Pharmacies that dispense SILIQ must be certified.**
   a. To become certified to dispense SILIQ, pharmacies must:
      i. Designate an authorized representative to complete the enrollment process by submitting the completed *SILIQ REMS Program Pharmacy Enrollment Form* on behalf of the pharmacy.
      ii. Ensure that the authorized representative oversees implementation and compliance with the SILIQ REMS Program requirements by the following:
          1) Review and complete the *SILIQ REMS Program Pharmacy Enrollment Form.*
          2) Ensure all relevant staff involved in the dispensing of SILIQ are informed of the SILIQ REMS Program requirements as described in the *SILIQ REMS Program Pharmacy Enrollment Form.*
      3) Put processes and procedures in place to ensure the following requirements are completed prior to dispensing SILIQ:
a) Verify the prescriber is certified and the patient is enrolled in the SILIQ REMS Program by calling the SILIQ REMS Program or by accessing the SILIQ REMS Program Website.

b. As a condition of certification, the certified pharmacies must:
   i. Recertify in the SILIQ REMS Program if the pharmacy designates a new authorized representative.
   ii. Dispense SILIQ to patients only after obtaining authorization by calling the SILIQ REMS Program or by accessing the SILIQ REMS Program Website. The authorization confirms the following:
       1) The prescriber is certified in the SILIQ REMS Program; and
       2) The patient is enrolled in the SILIQ REMS Program
   iii. Maintain documentation that all processes and procedures are in place and are being followed for the SILIQ REMS Program and provide upon request to Bausch Health, FDA, or a third party acting on behalf of Bausch Health or FDA.
   iv. Comply with audits by Bausch Health, FDA, or a third party acting on behalf of Bausch Health or FDA, to ensure that all processes and procedures are in place and are being followed for the SILIQ REMS Program.

c. Bausch Health must:
   i. Ensure that pharmacies that dispense SILIQ are specially certified, in accordance with the requirements described above.
   ii. Provide all the following mechanisms for pharmacies to complete certification for the SILIQ REMS Program: online, by email, and by fax.
   iii. Ensure that pharmacies are notified when they have been certified by the SILIQ REMS Program.
   iv. Ensure that certified pharmacies are provided access to the database of certified prescribers and enrolled patients.
   v. Verify every year that the authorized representative’s name and contact information correspond to those of the currently designated authorized representative for the certified pharmacy. If different, the pharmacy must be required to recertify with a new authorized representative.

The following materials are part of the REMS and are appended:

- **SILIQ REMS Program Pharmacy Enrollment Form**
- **SILIQ REMS Program Website** (www.SILIQREMS.com)

3. **SILIQ must be dispensed to patients with evidence or other documentation of safe-use conditions.**

   a. To become enrolled in the SILIQ REMS Program, a patient must sign a **SILIQ REMS Program Patient-Prescriber Agreement Form** indicating that he/she has:
      i. Received and has read the **SILIQ REMS Program Patient-Prescriber Agreement Form** with their prescriber.
      ii. Received counseling from the prescriber regarding:
          1) the observed risk of suicidal ideation and behavior (SIB)
          2) the importance of keeping the **SILIQ REMS Program Patient Wallet Card** with them at all times
3) the need to seek medical attention should they experience emergence or worsening of suicidal ideation and behavior

iii. Received the SILIQ REMS Program Patient Wallet Card

b. Bausch Health must:
   i. Provide all of the following mechanisms for the certified prescribers to be able to submit the completed SILIQ REMS Program Patient-Prescriber Agreement Form to the SILIQ REMS Program: online, by email, and by fax.

The following materials are part of the REMS and are appended:
- SILIQ REMS Program Patient Wallet Card
- SILIQ REMS Program Patient-Prescriber Agreement Form

B. Implementation System

1. Bausch Health must ensure that SILIQ is only distributed to certified pharmacies by:
   a. Ensuring that wholesalers/distributors who distribute SILIQ comply with the program requirements for wholesalers/distributors. The wholesalers/distributor must:
      i. Put processes and procedures in place to verify, prior to distributing SILIQ, that the pharmacies are certified.
      ii. Train all relevant staff on the SILIQ REMS Program requirements.
      iii. Comply with audits by Bausch Health, FDA, or a third party acting on behalf of Bausch Health or FDA to ensure that all processes and procedures are in place and are being followed for the SILIQ REMS Program. In addition, wholesalers/distributors must maintain documentation to support that all processes and procedures are in place, being followed, and make the documentation available for audits.
      iv. Provide distribution data to Bausch Health to verify compliance with the REMS.

   b. Ensuring that wholesalers/distributors maintain distribution records of all shipments of SILIQ and provide the data to Bausch Health.

2. Bausch Health must monitor distribution data to ensure all the processes and procedures are in place and functioning to support the requirements of the SILIQ REMS Program.

3. Bausch Health must audit the wholesalers/distributors within 90 calendar days after the wholesaler/distributor is authorized to ensure that all processes and procedures are in place and functioning to support the requirements of the SILIQ REMS Program.

4. Bausch Health must maintain a validated, secure database of prescribers and pharmacies that are certified to dispense SILIQ in the SILIQ REMS Program. Bausch Health will make the list of certified prescribers available to patients via the SILIQ REMS Program Website (www.SILIQREMS.com).

5. Bausch Health must maintain a validated, secure database of patients who are enrolled in the SILIQ REMS Program.

6. Bausch Health must maintain records of SILIQ certified prescribers, certified pharmacies, and enrolled patients to meet REMS requirements.

7. Bausch Health must maintain a SILIQ REMS Program Call Center (855-511-6135) and SILIQ REMS
Program Website (www.SILIQREMS.com). The SILIQ REMS Program Website must include the capability to confirm patient authorization status, and the option to print the Prescribing Information, Medication Guide, and SILIQ REMS materials. The SILIQ product website must include a prominent REMS-specific link to the SILIQ REMS Program Website. The SILIQ REMS Program Website must not link back to the product website(s).

8. Bausch Health must ensure that the SILIQ REMS Program Website is fully operational, including the capability to complete prescriber and pharmacy certification and patient enrollment online; online confirmation of patient authorization functionality; and the REMS materials listed in or appended to the SILIQ REMS document are available through the SILIQ REMS Program Website and by calling the SILIQ REMS Program Call Center.

9. Bausch Health must monitor on an ongoing basis the certified pharmacies to ensure the requirements of the SILIQ REMS Program are being met. Bausch Health must institute corrective action if noncompliance is identified and decertify pharmacies that do not maintain compliance with the REMS requirements.

10. Bausch Health must maintain an ongoing annual audit plan that involves certified pharmacies.

11. Bausch Health must audit 20% or one, whichever is greater, of the certified pharmacies within 90 calendar days after the pharmacy places its first order of SILIQ to ensure that all processes and procedures are in place and functioning to support the requirements of the SILIQ REMS Program. The certified pharmacies must be identified in Bausch Health’s ongoing annual audit plan. Bausch Health must institute corrective action if noncompliance is identified.

12. Bausch Health must take reasonable steps to improve implementation of and compliance with the requirements in the SILIQ REMS Program based on monitoring and evaluation of the SILIQ REMS Program.

III. TIMETABLE FOR SUBMISSION OF ASSESSMENTS

Bausch Health must submit REMS assessments to the FDA at 6 months and 12 months and annually thereafter from the date of the initial approval of the REMS (February 15, 2017). To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 calendar days before the submission date for that assessment. Bausch Health must submit each assessment so that it will be received by the FDA on or before the due date.