



## TEGSEDI® REMS Prescriber Enrollment Form

TEGSEDI is available only through the TEGSEDI REMS, a restricted distribution program. Only prescribers, pharmacies, and patients enrolled in the program can prescribe, dispense, and receive TEGSEDI.

### Instructions:

- 1) Review the TEGSEDI Prescribing Information (PI), the *Program Overview*, and the *Prescriber Training*.
- 2) Complete the *Prescriber Knowledge Assessment* and this *Prescriber Enrollment Form*.
- 3) Submit the completed *Prescriber Knowledge Assessment* and this enrollment form:
  - Online at [www.TEGSEDIrems.com](http://www.TEGSEDIrems.com)
  - Or Fax: 1-855-4TEGREMS (1-855-483-4736)

Please complete all mandatory fields on this form to avoid a delay in the enrollment process. Upon completion of these steps, the REMS will notify you of successful certification.

### PRESCRIBER AGREEMENT

By signing below, I agree TEGSEDI is only available through the REMS and I must comply with the following REMS requirements:

#### I have:

- Reviewed the Prescribing Information, *REMS Program Overview* and the *Prescriber Training*
- Successfully completed the *Prescriber Knowledge Assessment* and submitted it to the REMS

#### Before treatment initiation (first dose) I must:

- Counsel the patient, using the *Patient Guide* and *Wallet Card*, on how to recognize and respond to signs and symptoms of serious bleeding and glomerulonephritis and the need to have their platelets and renal function monitored
- Provide the patient with the *Patient Guide* and *Wallet Card*
- Assess the patient's platelet count, estimated glomerular filtration rate (eGFR), urinalysis, and urine protein to creatinine ratio (UPCR) and the appropriateness of initiating treatment
- Enroll the patient by completing and submitting the *Patient Enrollment Form* to the REMS. Provide a completed copy of the form to the patient

#### During treatment weekly or more frequently as described in the Prescribing Information I must:

- Assess the patient's platelet count and appropriateness of continuing treatment

#### During treatment every 2 weeks I must:

- Assess the patient's eGFR, urinalysis, and UPCR and appropriateness of continuing treatment

#### During treatment every 90 days I must:

- Assess the patient's platelet count, signs and symptoms of thrombocytopenia, and appropriateness of continuing treatment. Document and submit to the REMS using the *Patient Status Form*
- Assess the patient's eGFR, urinalysis, UPCR, signs and symptoms of renal toxicity, and appropriateness of continuing treatment. Document and submit to the REMS using the *Patient Status Form*

#### For eight weeks after treatment is discontinued, I must:

- Assess the patient's platelet count weekly, or more frequently as described in the Prescribing Information
- Assess the patient's eGFR, urinalysis, and UPCR every 2 weeks

#### Eight weeks after treatment is discontinued, I must:

- Assess the patient's platelet count and signs and symptoms of thrombocytopenia. Document and submit to the REMS using the *Patient Status Form*
- Assess the patient's eGFR, urinalysis, UPCR, and signs and symptoms of renal toxicity. Document and submit to the REMS using the *Patient Status Form*

#### At all times, I must:

- Report events of severe thrombocytopenia, serious bleeding with severe thrombocytopenia, and glomerulonephritis by contacting the REMS by phone, online, and fax or by using the *Patient Status Form* online and by fax
- Report treatment discontinuation or transfer of care to the REMS using the *Patient Status Form*

#### I understand and acknowledge that:

- I will only be able to prescribe TEGSEDI if certified in the REMS
- I am responsible for safeguarding my credentials for the REMS website. I will not share my credentials for the REMS website or allow others to sign into the website using my credentials
- I will allow Sobi, Inc. and its agents to contact me via phone, mail, fax, or email to support administration of the REMS
- I understand that if I fail to maintain compliance with the requirements of the TEGSEDI REMS, I may no longer be able to prescribe TEGSEDI

