FILSPARI® REMS OUTPATIENT PHARMACY ENROLLMENT FORM

Instructions:

1. Review the **Prescriber and Pharmacy Guide**.
2. Enroll by completing and submitting this **Outpatient Pharmacy Enrollment Form** to the REMS by fax to 1-833-483-4736.

Due to the risk of hepatotoxicity, FILSPARI is available only through a restricted program called the FILSPARI REMS (Risk Evaluation and Mitigation Strategy). All outpatient pharmacies that wish to stock FILSPARI must certify by enrolling in the FILSPARI REMS.

Complete all required fields on this form to avoid a delay in the enrollment process.

1. Outpatient Pharmacy Information *(*indicates required field)*

*Outpatient Pharmacy Name:			
*Facility National Provider Identifier (NPI) #:	Drug Enforcement Administration Number (DEA #):		
*Pharmacy Address Line #1:			
Pharmacy Address Line #2:			
*City:		*State:	*Zip:
*Phone:	*Fax:		

Pharmacy Ship To Contact

*First Name:	*Last Name:

Pharmacy Shipping Address, if different from above

*Address Line #1:			
Address Line #2:			
*City:		*State:	*Zip:
*Phone:	*Fax:		

2. Outpatient Pharmacy Authorized Representative Information *(*indicates required field)*

*First Name:	*Last Name:
Position/Title: ☐ Pharmacist ☐ Head of Pharmacy and Therapeutics (P&T) committee ☐ Other (please specify):_____	
*Credentials: ☐ RPh ☐ PharmD ☐ Other	
*Authorized Representative Phone:	*Fax:
*Authorized Representative Email:	*Contact Preference (please select one): ☐ Email ☐ Fax

3. Outpatient Pharmacy Authorized Representative Agreement

As the pharmacy authorized representative, to become certified to dispense FILSPARI, I must:

- Carry out the certification process and oversee implementation and compliance with the REMS on behalf of the pharmacy.
- Review the **Prescriber and Pharmacy Guide**.
- Certify by enrolling in the REMS by completing the **Outpatient Pharmacy Enrollment Form** and submitting it to the REMS.
- Train all relevant staff involved in dispensing on the REMS requirements using the **Prescriber and Pharmacy Guide**.
- Establish processes and procedures to verify the patient is enrolled and the prescriber is certified.
- Establish processes and procedures to document and submit confirmation of counseling on the risk of hepatotoxicity.
- Establish processes and procedures to verify and document the patient's liver testing is complete or the prescriber authorizes the refill.

Before dispensing FILSPARI, my pharmacy must:

- Verify the patient is enrolled and the prescriber is certified through the processes and procedures established as a requirement of the REMS.

Before dispensing FILSPARI; at initial dispense, then every 3 months, my pharmacy must:

- Counsel the patient on the risk of hepatotoxicity. Document and submit confirmation of counseling through the processes and procedures established as a requirement of the REMS.
- Verify and document the patient's liver testing is complete or the prescriber authorizes the refill through the processes and procedures established as a requirement of the REMS.

At all times, my pharmacy must:

- Dispense no more than a 90-days' supply.
- Report adverse events suggestive of hepatotoxicity to the REMS.
- Not distribute, transfer, loan, or sell FILSPARI, except to certified dispensers.
- Maintain and submit records of product dispensing to the REMS.
- Maintain records that all processes and procedures are in place and are being followed.
- Comply with audits carried out by Travere Therapeutics, Inc. or a third party acting on behalf of Travere Therapeutics, Inc. to ensure that all processes and procedures are in place and are being followed.

To maintain certification to dispense, my pharmacy must:

- Have a new authorized representative enroll by completing and submitting an **Outpatient Pharmacy Enrollment Form**, if the authorized representative changes.

Provide Signature Below

By signing below, I acknowledge the above agreements and my obligations as a FILSPARI outpatient pharmacy authorized representative and agree to oversee the implementation of and compliance with the REMS requirements for this pharmacy. I understand my personally identifiable information provided above will be shared with Travere Therapeutics, Inc., its agents or contractors and entered into a database for the FILSPARI REMS. I agree that I may be contacted in the future by mail, email, fax, and/or phone concerning FILSPARI, the FILSPARI REMS, and other FILSPARI programs and services.

*Authorized Representative Signature:	*Date (MM/DD/YYYY):

Healthcare providers should report adverse events suggestive of hepatotoxicity to the FILSPARI REMS at 1-833-513-1325. Report all other suspected adverse events or product quality complaints associated with FILSPARI to Travere Therapeutics, Inc. at 1-877-659-5518 or the FDA at 1-800-FDA-1088 or online at www.fda.gov/medwatch.

If you have any questions, require additional information, or need further copies of FILSPARI REMS materials, please visit the **REMS Website** at www.FILSPARIREMS.com, or call the FILSPARI REMS at 1-833-513-1325.