FILSPARI® REMS PATIENT ENROLLMENT FORM

To enroll in the FILSPARI REMS, complete and submit online at www.FILSPARIREMS.com or complete and fax this form to 1-833-483-4736.

1 Patient Information *(*indicates required field)*

*First Name:	Middle Initial:	*Last Name:	*Birthdate (MM-DD-YYYY):
*Address Line #1:			Address Line #2:
*City:			*State: / *Zip:
*Primary Phone:	Other Phone:		Email:

2 Patient Agreement *(*indicates required field)*

PATIENTS WHO CAN BECOME PREGNANT

Before treatment, I must:
- Review the ***Patient Guide***.
- Get a liver test and a pregnancy test.
- Receive counseling from my prescriber on the risk of liver problems, the signs and symptoms of liver problems, the need to contact my prescriber if I have any signs or symptoms of liver problems, and the need to complete liver testing monthly for the first 12 months, then every 3 months during treatment using the ***Patient Guide***.
- Receive counseling from my prescriber on the risk of serious birth defects, the need to use effective contraception during treatment and for one month following treatment discontinuation, the need to complete monthly pregnancy tests, the potential need for emergency contraception, and to immediately contact my prescriber if I miss a menstrual period or suspect that I am pregnant using the ***Patient Guide***.
- Enroll in the REMS by completing the ***Patient Enrollment Form*** with my prescriber. Enrollment information will be provided to the REMS.

During treatment; monthly for the first 12 months, then every 3 months, I must:
- Get a liver test.
- Adhere to the safe use condition: Communicate with the pharmacy to confirm completion of liver testing.

During treatment monthly, I must:
- Get a pregnancy test.
- Receive counseling from the pharmacy on the risks of liver problems and serious birth defects associated with FILSPARI treatment.
- Adhere to the safe use condition: Communicate with the pharmacy to confirm completion of pregnancy testing.

During treatment and after treatment discontinuation for one month, I must:
- Adhere to the safe use condition: Use effective contraception as described in the ***Patient Guide***.

After treatment discontinuation for one month, I must:
- Get a pregnancy test.

At all times, I must:
- Inform my prescriber if I have any signs or symptoms of liver problems as described in the ***Patient Guide***.
- Inform my prescriber immediately if I suspect I may be pregnant.
- Inform my prescriber if there is a change in my reproductive status.

PATIENTS WHO CANNOT BECOME PREGNANT

Before treatment, I must:
- Review the ***Patient Guide***.
- Get a liver test.
- Receive counseling from my prescriber on the risk of liver problems, the signs and symptoms of liver problems, the need to contact the prescriber if I have any signs or symptoms of liver problems, and the need to complete liver testing monthly for the first 12 months, then every 3 months during treatment using the ***Patient Guide***.
- Enroll in the REMS by completing the ***Patient Enrollment Form*** with my prescriber. Enrollment information will be provided to the REMS.

During treatment; monthly for the first 12 months, then every 3 months, I must:
- Get a liver test.
- Adhere to the safe use condition: Communicate with the pharmacy to confirm completion of liver testing.

During treatment monthly, I must:
- Receive counseling from the pharmacy on the risk of liver problems associated with FILSPARI treatment.

At all times, I must:
- Inform my prescriber if I have any signs or symptoms of liver problems as described in the ***Patient Guide***.
- Inform my prescriber if there is a change in my reproductive status.

I understand that my protected health information will be stored in a secure and confidential database and shared for the management of FILSPARI REMS.

I understand that I may be contacted by Travere Therapeutics and its agents about the FILSPARI REMS for voluntary participation in a research study to evaluate possible liver problems while I am receiving FILSPARI. Participation in the study is not required to be enrolled in the REMS or to receive FILSPARI.

*Patient Signature:	*Signature Date (MM-DD-YYYY):
*Parent/Legal Guardian Signature:	
Parent/Legal Guardian First Name (if signing on behalf of patient): / Parent/Legal Guardian Last Name:	Parent/Legal Guardian Email:

3 Prescriber Information *(*indicates required field)*

*First Name:	*Last Name:	*National Provider Identifier (NPI) #:

4 Prescriber Authorization *(*indicates required field)*

4A *Please indicate the patient's current reproductive status below. (Please see definitions of these terms below)

☐ **Patient Who Can Become Pregnant**

*If selected, has a negative pregnancy test result been confirmed prior to prescribing FILSPARI? ☐ Yes ☐ No

Note: The pharmacy will confirm completion of a pregnancy test prior to each dispense

OR

☐ **Patient Who Cannot Become Pregnant**

4B *For this patient, have you reviewed the results of their current liver testing? ☐ Yes ☐ No

Note: The pharmacy will confirm completion of a liver test prior to dispense

I certify that I have provided the appropriate counseling for patients and provided FILSPARI REMS materials. I will continue to fulfill my obligations under the FILSPARI REMS.

*Prescriber Signature:	*Signature Date (MM-DD-YYYY):

Definitions of Reproductive Potential Status

Patients Who Cannot Become Pregnant

- Patients with a uterus who are at Tanner Stages 1 and 2 are not considered to be of reproductive potential.
- Patients with a uterus who have passed through Menopause (as defined below).
- Other medical reasons for permanent, irreversible infertility.
- Patients without a uterus (including patients who were born male).

Patients Who Can Become Pregnant

- Patients with a uterus who have entered puberty and all patients who have a uterus and have not passed through Menopause (as defined below).
- For the purposes of the FILSPARI REMS, puberty includes those patients with a uterus who are at least Tanner Stage 3 and have not yet had a menses (premenarchal).
- For the purposes of the FILSPARI REMS, patients who have undergone tubal sterilization are classified as patients who can become pregnant.

Menopause

Menopause is defined as 12 months of spontaneous amenorrhea (not amenorrhea induced by a medical condition or medical therapy) or postsurgical from bilateral oophorectomy.

Prescriber Requirements Under the FILSPARI REMS

- I acknowledge that I have counseled the patient on the risk of hepatotoxicity and that FILSPARI is available only through a restricted distribution program under an FDA-required REMS using the ***Patient Guide***.
- I will assess the patient's liver function prior to initiation, monthly for the first 12 months, then every 3 months during treatment.
- I will evaluate the patient and agree to document any change in reproductive potential status by submitting a ***Change in Reproductive Potential Status Form*** within 10 business days of becoming aware of the change.

For Patients Who Can Become Pregnant

- I acknowledge that I have counseled the patient on the risk of embryo-fetal toxicity.
- I will assess the pregnancy status of the patient by ordering and reviewing a pregnancy test result prior to initiation, monthly during treatment prior to receiving each refill, and for one month after discontinuation of treatment in accordance with the FILSPARI REMS.

Healthcare providers should report adverse events suggestive of hepatotoxicity and pregnancies 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.