Tracleer® REMS Prescriber Enrollment and Agreement Form

Complete and fax this form to *Actelion Pathways*® at 1-866-279-0669.

Contact *Actelion Pathways* via phone at 1-866-ACTELION (1-866-228-3546).

PT2201502

Prescriber Information (please print)

First name | MI | Last name

☐ MD ☐ DO ☐ PA ☐ NP

Email address | NPI # | Professional designation

In the event you are unavailable, is there another person we can contact on your behalf? ☐ Yes ☐ No
If yes, please indicate.

Name | Phone

Office Practice/Clinic Information (please print)

Primary

Office practice/Clinic name | Affiliated hospital

Specialty | Office contact name | Office contact phone

Office email address | Phone | Fax

Address | City

State | ZIP | ☐ Phone ☐ Fax ☐ Email Preferred method of contact

Secondary

Office practice/Clinic name | Affiliated hospital

Specialty | Office contact name | Office contact phone

Office email address | Phone | Fax

Address | City

State | ZIP | ☐ Phone ☐ Fax ☐ Email Preferred method of contact

Tracleer REMS Prescriber Agreement

By signing below, you signify your understanding of the risks of Tracleer treatment and your obligations as a Tracleer prescriber to educate your patients about the Tracleer REMS (Risk Evaluation and Mitigation Strategy) Program, monitor them appropriately, and report any adverse events, including hepatotoxicity, and any pregnancies to the Tracleer REMS Program.

Signature | Date

Tracleer REMS Prescriber Enrollment Requirements

Specifically, you attest to the following:

- I have read the Tracleer Prescribing Information, the *Tracleer Medication Guide*, and the *Prescriber and Pharmacy Guide for the Tracleer REMS Program* and agree to comply with the Tracleer REMS Program requirements
- I agree to enroll all patients into the Tracleer REMS Program
- I will:
  - Advise all patients that Tracleer is only available through a restricted distribution program called the Tracleer REMS Program
  - Counsel patients on the risk of hepatotoxicity and review the *Tracleer Medication Guide* and the *Tracleer REMS Guide for Patients* with the patient
  - Order and review liver function tests (ALT/AST/bilirubin) prior to initiating treatment and monthly during treatment
  - Counsel patients to immediately contact their healthcare provider if they have signs or symptoms of liver injury such as nausea, vomiting, fever, unusual tiredness, stomach area (abdominal) pain, or yellowing of the skin or the whites of the eyes (jaundice)
  - Determine the reproductive potential status of female patient using the definitions provided in the *Prescriber and Pharmacy Guide for the Tracleer REMS Program*
  - Order and review pregnancy tests for Females of Reproductive Potential prior to initiating treatment with Tracleer, monthly during treatment, and for one month after stopping treatment
  - Counsel Females of Reproductive Potential (FRP) on the risks of Tracleer, including the risk of serious birth defects, and review the *Tracleer Medication Guide* and the *Tracleer REMS Guide for Patients* with the patient
  - Counsel FRPs to use reliable contraception during Tracleer treatment, and for one month after stopping treatment; and discuss their medical options in the event of unprotected sexual intercourse or known or suspected contraceptive failure
  - Counsel FRPs to immediately contact their healthcare provider if they miss a menstrual period or suspect pregnancy
  - Counsel the Pre-pubertal Female patients and/or parent/guardian on the risks of Tracleer, including the risk of serious birth defects, and review the *Tracleer Medication Guide* with the patient and parent/guardian
  - Counsel Pre-pubertal Female patients and/or parent/guardian to immediately contact her healthcare provider if the patient begins to menstruate
  - Verify the reproductive potential status annually for Pre-pubertal Females who are at least 8 years of age and older by submitting a *Tracleer REMS Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form*
  - Report any change or misclassification in reproductive potential status by submitting a *Tracleer REMS Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form* within 10 business days of becoming aware of the change
  - Counsel patients who fail to comply with the Tracleer REMS Program requirements
  - Notify Actelion of any adverse events, including hepatotoxicity, and report any pregnancies at 1-866-ACTELION (1-866-228-3546)

Please visit www.TracleerREMS.com or call 1-866-ACTELION (1-866-228-3546) for more information about the Tracleer REMS Program.