

December 2016

## IMPORTANT CHANGES TO THE TRACLEER® REMS PROGRAM

Dear Certified Tracleer Prescriber or Pharmacist,

Actelion Pharmaceuticals US, Inc. ("Actelion"), would like to inform you of important changes to the Tracleer REMS Program.

### Changes to the Tracleer REMS Program December 2016

- Revised Form: *Tracleer Patient Enrollment and Consent Form*  
(available on [www.TracleerREMS.com](http://www.TracleerREMS.com))
- New Form: *Tracleer Patient Enrollment and Consent Form for VA use*  
(available on [www.TracleerREMS.com](http://www.TracleerREMS.com))
- Revised Guide: *Prescriber and Pharmacy Guide for the Tracleer REMS Program*  
(available on [www.TracleerREMS.com](http://www.TracleerREMS.com))

### Impact on Tracleer Prescribers

As a certified prescriber, you will now be required to classify each of your female patients into one of the following groups (see [TracleerREMS.com](http://TracleerREMS.com) and *Tracleer REMS Patient Enrollment and Consent Form* for detailed definitions):

- Female of Reproductive Potential
- Female of Non-Reproductive Potential
  - Pre-pubertal Female
  - Post-menopausal Female
  - Female with other medical reason for permanent, irreversible infertility

This classification of patients may make it easier to identify which patients do not need to have monthly pregnancy tests.

You will now be required to complete a *Tracleer REMS Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form* for a change in reproductive status for any female patient and submit the form to Actelion Pathways® within 10 business days of your awareness of the change. The *Prescriber and Pharmacy Guide for the Tracleer REMS Program* has been revised to describe the process and is available on [www.TracleerREMS.com](http://www.TracleerREMS.com).

The Tracleer REMS forms have been updated to include these new requirements and are available to you on the [www.TracleerREMS.com](http://www.TracleerREMS.com) or by contacting Actelion Pathways on 1-866-ACTELION (1-866-228-3546).

## What Has Not Changed with the Tracleer REMS Program

- All patients on Tracleer must be enrolled in the Tracleer REMS Program by their certified prescriber and comply with the requirements of the REMS Program
- All prescribers must:
  - be specially certified in the Tracleer REMS Program to prescribe Tracleer to patients in the outpatient or inpatient setting
  - counsel and educate patients about: the risks of Tracleer, the importance of monthly liver function and pregnancy testing, and the need for females of reproductive potential to use reliable methods of contraception and not to become pregnant
  - monitor patients' liver function and pregnancy test results
- Only specialty pharmacies that have been specially certified in the Tracleer REMS Program may dispense Tracleer in the outpatient setting
- Only inpatient pharmacies that have been certified in Tracleer REMS Program may dispense Tracleer in the inpatient setting

For more information regarding inpatient pharmacy certification, please see **[www.TracleerREMS.com](http://www.TracleerREMS.com)**, or contact *Actelion Pathways* at 1-866-ACTELION (1-866-228-3546) for documentation and certification information.

## Adverse Event Reporting

To report suspected adverse reactions, contact Actelion at 1-866-ACTELION (1-866-228-3546), or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

A copy of the revised full prescribing information and Medication Guide for Tracleer are enclosed for your reference. If you have any questions, please contact your local Tracleer representative or Actelion at the number above.

Sincerely,

Actelion Pharmaceuticals US, Inc.

