Tracleer® (bosentan) Enrollment and Renewal

Check one: ☐ **Enrollment** ☐ **Renewal**

PO Box 826, South San Francisco, CA 94083-0826 | Phone 1-866-ACTELION (1-866-228-3546) or Fax 1-866-279-0669

Once complete, submit this form to PAH Pathways.™ The information will be entered into the Tracleer Access Program (T.A.P.®) database and forwarded to the specialty pharmacy you designate below. The specialty pharmacy will follow up as needed with prescribers and patients.

Patient Information

First name:	MI:	Last name:	Gender: ☐ Male ☐ Female
SSN:		DOB:	Phone #:
Address:		City:	State: ZIP:
Legal guardian/emergency contact:		Relationship:	Phone #:
Shipping directions: ☐ Physician office ☐ Patient's home ☐ Hospital		Shipping attn:	
Shipping address:		City:	State: ZIP:

Diagnosis: Pulmonary arterial hypertension (check subtypes): ☐ Familial ☐ Idiopathic ☐ Scleroderma ☐ HIV ☐ Lupus ☐ Portal hypertension ☐ Congenital heart defects ☐ Pulmonary hypertension—other etiologies: _____
☐ Other: _____

Required: Please submit copies of patient's current medical and prescription cards with this form.

Insurance Information

Primary insurance company:			Phone #:
Name of insured:		Policy #:	Group/Policy #:
Prescription coverage name:	Phone #:	Policy #:	Group/Policy #:

Indicate specialty pharmacy preference: _____

For a current list of pharmacies, call 1-866-228-3546. If no preference is indicated, this referral will be sent to the appropriate specialty pharmacy based on the patient's existing benefits.

I have read and agreed to the Patient Agreement on the back of this form. I have reviewed the Medication Guide with my prescriber, I consent to be enrolled in the Tracleer Access Program, and I agree to comply with the program for as long as I am prescribed Tracleer.

Patient/guardian signature: _____ Date: _____

Prescriber and Prescription Information

First name:	MI:	Last name:	Degree:
DEA #:		NPI:	

Complete section below only if you are a new prescriber or your contact information has changed.

Name of facility:	Specialty:	Tax ID #:	State license #:
Office contact (name and phone):		Phone #:	Fax #:

Primary address:	City:	State:	ZIP:	E-mail:

For the patient indicated on this form, please indicate whether:

1. You have reviewed pretreatment liver function tests. ☐ Yes ☐ No
2. If a female, she is of childbearing potential. ☐ Yes ☐ No
3. If a female of childbearing potential, you have confirmed a pretreatment negative pregnancy test. ☐ Yes ☐ No

☐ Tracleer 62.5 mg (66215-0101-06) Refills #: _____

☐ Tracleer 125 mg (66215-0102-06) Refills #: _____ Dispense as Written

Directions for use:

Prescriber signature: _____ Date: _____

Prescriber Certification—My signature below certifies that:

1. I have read and understood the communication and educational materials for prescribers regarding the risks of Tracleer, and agree to document that I:
   - –Reviewed and discussed the Medication Guide and the risks of bosentan (including the risks of teratogenicity and hepatotoxicity) with my patients prior to prescribing Tracleer.
   - –Reviewed pretreatment liver function tests (ALT/AST/bilirubin) and confirmed that my patients are not pregnant (if applicable), and I agree to order and monitor monthly liver function tests and, if applicable, pregnancy tests.
   - –Educated and counseled females of childbearing potential **(see definition on reverse side)** to notify me if they suspect they may be pregnant.
   - –Educated and counseled females of childbearing potential about the need to use reliable methods of contraception **(see table on reverse side)** during treatment with Tracleer and for one month after treatment discontinuation.
2. I will notify Actelion Pharmaceuticals US, Inc., and/or the FDA, of any adverse events, including hepatotoxicity, and report any pregnancy during treatment with Tracleer.
3. I will counsel my patients who fail to comply with the program requirements.
4. I will renew my patients' prescriptions annually by completing and submitting a new form for patients continuing therapy.

Prescriber signature: _____ Date: _____

BEFORE SIGNING, SEE IMPORTANT SAFETY INFORMATION ON BACK.

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Patient Agreement

- I have reviewed the Medication Guide with my healthcare provider. I understand that a Medication Guide will be provided to me each time I receive a prescription for Tracleer, and that I must read it each time because it may have new information important to my treatment.
- I have been informed of the risks of treatment with Tracleer, including the risks of liver injury and birth defects. I understand that I will be contacted by Actelion, its agents, and/or a healthcare provider to receive counseling on the risks of Tracleer treatment, to ensure that I am completing the required liver function tests and pregnancy tests (for females of childbearing potential—see definition below) and, if I am a female who becomes pregnant, to obtain information about my pregnancy.
- I agree to notify Actelion or my specialty pharmacy if I should change prescribers.
- I agree to have monthly blood tests as ordered by my healthcare provider for as long as I take Tracleer.
- I authorize my healthcare providers, health plans, other payers, and pharmacies to disclose my personal, medical, and health information to Actelion Pharmaceuticals US, Inc., and its employees, distributors, agents, and contractors ("Actelion"), and I authorize Actelion to use and disclose this information for use in implementing T.A.P. including to 1) establish my benefit eligibility; 2) communicate with my healthcare providers, health plans, other payers, and pharmacies about my medical care; 3) provide support services, including facilitating the provision of Tracleer to me; and 4) help find ways to pay for Tracleer, or for treatment or healthcare operations in progress.
- I understand that I may be contacted by Actelion or its delegates regarding important safety surveys while I am taking Tracleer.
- I understand that Actelion does not promise to find ways to pay for my Tracleer, and I know that I am responsible for the costs of my care.
- I understand that once my health information has been disclosed to Actelion, privacy laws may no longer restrict its use or disclosure; however, Actelion agrees to protect my information by using and disclosing it only for the purposes described above or as required by law.
- I acknowledge and agree that, although Actelion will have access to my personal health information, Actelion will not be providing counseling or medical advice regarding my condition. I further understand that all questions regarding my medical and health conditions should be discussed with my healthcare provider.

Definition of Female of Childbearing Potential (FCBP)

Female patients who are physically capable of becoming pregnant include those who are pubertal and have not yet had menses (premenarchal, Tanner stage 3, 11.5 to 13 years of age), perimenopausal and have had spontaneous menses in the last 24 months, and nonmenopausal who have not had a hysterectomy, bilateral oophorectomy, or medically documented ovarian failure.

Female patients who are not considered to be of childbearing potential are surgically sterile (both ovaries and/or uterus removed), postmenopausal (no menstrual period for longer than 24 consecutive months, confirmed by their healthcare provider), or incapable of pregnancy (confirmed by their healthcare provider).

Reliable methods of contraception during treatment with Tracleer

<table>
<tr><th>Methods to use alone</th><th>Hormone
(choose 1 and use with a barrier method)</th><th>Barrier
(use both OR choose 1 and use with a hormone method)</th></tr>
<tr><td rowspan="2">• Intrauterine devices (IUDs)
—Copper T 380A IUD
—LNg-20 IUS
(progesterone IUD)

• Tubal sterilization</td><td>• Estrogen and progesterone
—Oral contraceptives
—Transdermal patch
—Vaginal ring

• Progesterone only
—Injection
—Implant</td><td>• Male condom with spermicide

• Diaphragm with spermicide
OR
Cervical cap with spermicide</td></tr>
<tr><td colspan="2">A partner's vasectomy still requires 1 additional method of contraception.</td></tr>
</table>

COMPLETION OF THIS FORM IS ENTIRELY VOLUNTARY.
IT IS NOT REQUIRED FOR PARTICIPATION IN THE TRACLEER ACCESS PROGRAM

Authorization for Use or Disclosure of Health Information

Fax To: 1-866-279-0669

Patient Name: _____ Date of Birth: _____

I have elected to participate in the following program(s):

- ☐ **Sure Steps**™ is a patient support and educational program for patients with pulmonary arterial hypertension who are on Actelion PAH therapies.
- ☐ **LabTrac**™ is a program designed to assist your physician in managing your care. LabTrac allows your physician to centrally review all of your laboratory results associated with your treatment on Tracleer.

By signing below, I authorize Actelion Pharmaceuticals US, Inc., and agents operating the above-described Programs (collectively, "Actelion") to use and disclose any and all of my individually identifiable health information, including, but not limited to, any and all spoken or written facts about my health, medications, insurance benefits, and all records maintained by Actelion in connection with the Programs ("Health Information"), as described in this authorization.

I agree that Actelion may use and disclose my Health Information to Program representatives and third parties that work with Actelion (the "Authorized Persons") in order for the Authorized Persons to provide me with marketing, promotional or educational information with respect to the Programs, PAH, related conditions and/or treatment options (the "Information"). I agree that I may be contacted by the Authorized Persons by phone, mail, e-mail or through other means with respect to the Information. I understand that Actelion does not sell my Health Information to the Authorized Persons but that the Authorized Persons may receive remuneration from Actelion in connection with their involvement with the Programs, including the dissemination of the Information.

I understand and agree that the Authorized Persons may use and see my Health Information for the purposes described above. I understand that my Health Information may also be disclosed as needed to deal with safety, my treatment, adverse events, and related issues to the extent allowed under applicable law or as previously consented to in writing by me. I understand that if my Health Information is disclosed as allowed in this authorization, it may be redisclosed by the Authorized Persons and such redisclosure may not be protected by federal and state privacy laws.

This authorization expires ten (10) years from the date I sign this document. If I change my mind before that time and do not want Actelion to continue to share my Health Information in connection with the above-referenced Programs, I can notify Actelion of such revocation in writing, signed by me or my personal representative on my behalf and delivered to PAH Pathways c/o Actelion at 5000 Shoreline Court, Suite 200, South San Francisco, CA 94080. If I notify Actelion in writing to stop sharing my Health Information in connection with the above-referenced Programs, such notice will be effective upon receipt by Actelion but will not change any actions that Actelion or others took in reliance upon this authorization before my effective revocation of this authorization.

I know that I may refuse to sign this authorization. My decision not to sign this authorization or to, at any time, revoke this authorization will not affect my ability to get treatment from my healthcare providers, or to seek payment or eligibility for benefits.

I understand that I have a right to receive a copy of this authorization. **I agree that a copy of this authorization may be treated as a signed original.**

Patient signature: _____ **Date:** _____

Personal Representatives Section: If this form is signed by someone who is not the participant listed at the top of this authorization, describe the signer's legal authority to act for the participant:

_____

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PAHPathways™
ACTELION SERVICES & SUPPORT

Tracleer Access Program (T.A.P.®)

If you have questions about Tracleer enrollment and renewal, or if you would like more information about Tracleer, you can reach PAH Pathways, which administers T.A.P., by calling toll-free at 1-866-ACTELION (1-866-228-3546).

ACTELION