Letairis Risk Evaluation and Mitigation Strategy (REMS) Program

Prescriber Enrollment and Agreement Form

CLEAR FORM

To be enrolled into the Letairis REMS Program, complete and submit this form.

Complete the form online at www.letairisrems.com or fax this form to 1-888-882-4035.

1 Prescriber Information

First Name:	Middle Initial:	Last Name:	Suffix:
Specialty:	Name of Facility:	Office Contact (First and Last Name):	
Address:	City:	State:	ZIP: –
E-mail:	Phone: ( ) –	Fax: ( ) –	
State License #:	NPI #:		

2 Prescriber Agreement

By signing below, you signify your understanding of the risks of Letairis® (ambrisentan) treatment and your obligation as a Letairis prescriber to educate your female patients about these risks, counsel them on risk reduction, monitor them appropriately, and report adverse events to the Letairis REMS Coordinating Center. Specifically, you attest to the following:

- I have read the Prescribing Information and the *Prescriber Guide for the Letairis REMS Program* and agree to comply with the Letairis REMS Program requirements
- I agree to enroll all female patients into the Letairis REMS Program
- I will determine the reproductive potential status of all female patients using the definitions provided in the *Prescriber Guide for the Letairis REMS Program*
- I will advise all female patients that Letairis is only available through a restricted distribution program called the Letairis REMS Program
- I will counsel Females of Reproductive Potential on the risks of Letairis, including the risk of serious birth defects, and review the *Letairis REMS Program Guide for Female Patients* with the patient
- I will counsel the Pre-Pubertal Female patient and parent/guardian on the risks of Letairis, including the risk of serious birth defects, and review the *Letairis REMS Program Guide for Female Patients* with the patient and parent/guardian
- I will verify the reproductive potential status annually for Pre-Pubertal Females who are 8 years of age and older
- I will order and review pregnancy tests for Females of Reproductive Potential prior to initiating treatment with Letairis, monthly during treatment, and for 1 month after stopping treatment
- I agree to report any change in reproductive potential status by submitting a *Change in Reproductive Potential Status and Pre-Pubertal Annual Verification Form* within 10 business days of becoming aware of the change
- I will counsel Females of Reproductive Potential to use highly reliable contraception during Letairis treatment, and for 1 month after stopping treatment, and the need to use emergency contraception if required
- I will counsel female patients who fail to comply with the Letairis REMS Program requirements
- I will notify the Letairis REMS Coordinating Center of any adverse events, or if any patient becomes pregnant during Letairis treatment or within 1 month after stopping treatment

REQUIRED	Prescriber Signature: X	Date: / /

Please visit **www.letairisrems.com** or call **1-866-664-5327** for more information about the Letairis REMS Program.

GILEAD

Letairis®
ambrisentan
5 mg and 10 mg Tablets