Opsumit® REMS Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form

NOTE: THIS FORM SHOULD NOT BE USED TOGETHER WITH THE ENROLLMENT FORM.
USE IT ONLY TO REPORT A CHANGE IN REPRODUCTIVE STATUS OR FOR PRE-PUBERTAL ANNUAL VERIFICATION.

Complete this form to:
1) Change the reproductive status of any female patient within 10 business days of awareness of the change in reproductive status
2) Complete the annual verification of the reproductive potential status for Pre-pubertal Females 8 years of age or older

Fax this form to *Actelion Pathways®* at 1-866-279-0669.

Prescriber must complete this form within 10 business days of awareness of the change in reproductive status.

Patient Information (please print)

Patient Opsumit ID

First name | MI | Last name

Address

City | State | ZIP

Birth date | Phone

Prescriber Information (please print)

First name | MI | Last name

NPI #

Address

City | State | ZIP

Phone | Fax

Opsumit Prescriber ID (if available)

Office contact and email address (optional)

Definitions of Reproductive Potential Status

Females of Reproductive Potential

- Females of reproductive potential include girls who have entered puberty and all females who have a uterus and have not passed through menopause (as defined below)
- For the purposes of this REMS, puberty includes those girls who are at least Tanner Stage 3 and have not yet had a menses (premenarchal)

Females of Non-Reproductive Potential

- Pre-pubertal females: Females who are at Tanner Stages 1 and 2 are not considered to be of reproductive potential
- Post-menopausal females: Females who have passed through menopause. Menopause is defined as 12 months of spontaneous amenorrhea (not amenorrhea induced by a medical condition or medical therapy) or post-surgical form bilateral oophorectomy
- Females with other medical reasons for permanent, irreversible infertility

Select the most appropriate reason for submitting this form.

(For reference, please see the Definitions of Reproductive Potential Status)

Change in Status

- **Based on definitions of reproductive potential status, patient is (please check one):**
  - ☐ Female of Reproductive Potential
  - ☐ Female of Non-Reproductive Potential – Patient is pre-pubertal
  - ☐ Female of Non-Reproductive Potential – Patient is post-menopausal
  - ☐ Female of Non-Reproductive Potential – Other medical reasons for permanent, irreversible infertility
- **Reason for change in classification (please check one):**
  - ☐ Physiological transition
  - ☐ Medical/surgical (please specify): _____
  - ☐ Other (please specify): _____
- **Annual Verification**
  - ☐ Patient remains a Pre-pubertal Female (8 years of age or older)

Prescriber acknowledgement (REQUIRED)

By signing, I certify that the patient's reproductive status as noted above is accurate, and that I will comply with the REMS requirements for my patient's reproductive potential status.

Prescriber signature | Title (MD/PA/NP, etc) | Date

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

©2015 Actelion Pharmaceuticals US, Inc. All rights reserved. MRC-2015-REMS-0040

Reference ID: 3890050

FO2201512