Appendix 6 *CAPRELSA Patient Brochure*

Reference ID: 4098675

Caprelsa®
(vandetanib) Tablets

CAPRELSA® PATIENT BROCHURE

What do you need to know about CAPRELSA?

What is CAPRELSA?

CAPRELSA is a prescription medicine used to treat medullary thyroid cancer that cannot be removed by surgery or that has spread to other parts of the body.

What are the most serious risks of CAPRELSA?

CAPRELSA can cause a change in the electrical activity of your heart called QT prolongation, which can cause irregular heartbeats that may lead to death.

You should not take CAPRELSA if you have had a condition called long QT syndrome since birth.

Your prescriber should perform the following tests:

- Check the levels of your blood potassium, calcium, magnesium, and thyroid-stimulating hormone (TSH)
- Check the electrical activity of your heart, using a device called an electrocardiogram (ECG)

These tests should be performed before starting CAPRELSA and regularly during CAPRELSA treatment.

What are the signs and symptoms of QT prolongation?

- Feeling faint
- Feeling light-headed
- Feeling your heart beating irregularly

Call your prescriber right away if you experience these signs or symptoms.

The CAPRELSA REMS Program

Because of the risk of QT prolongation, CAPRELSA is only available through a program called the CAPRELSA Risk Evaluation and Mitigation (REMS) Program.

Your prescriber will discuss the benefits and risks of CAPRELSA with you.

How do I receive CAPRELSA?

CAPRELSA is only available through a REMS Certified Pharmacy. Your prescriber will submit your CAPRELSA prescription to Biologics, Inc. The certified pharmacy will call you to arrange the date to ship CAPRELSA to you. You can contact Biologics, Inc. about your prescription at 1-800-367-4999.

This brochure only discusses the most serious risks of CAPRELSA and the CAPRELSA REMS Program. For more information about CAPRELSA please see the CAPRELSA Medication Guide available at www.caprelsarems.com.

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(vandetanib) Tablets

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