



IMPORTANT DRUG WARNING

SUBJECT: Serious Risks of QT prolongation, Torsades de pointes and Sudden death for Caprelsa® (vandetanib); FDA required restricted distribution program.

DATE

Dear (Medical Society):

AstraZeneca Pharmaceuticals LP would like to inform you and your membership of the approval of CAPRELSA (vandetanib), a new kinase inhibitor that has been approved by the Food and Drug Administration (FDA) for the treatment of symptomatic or progressive medullary thyroid cancer in patients with unresectable locally advanced or metastatic disease. Use of CAPRELSA in patients with indolent, asymptomatic or slowly progressing disease should be carefully considered because of the treatment related risks of CAPRELSA.

CAPRELSA can prolong the QT interval and cases of Torsades de pointes and sudden death were reported in clinical trials. Because of these risks, CAPRELSA is available only through a restricted distribution program called CAPRELSA REMS Program. **Under the CAPRELSA REMS Program, only prescribers and pharmacies enrolled in the program can prescribe and dispense CAPRELSA.**

In order to prescribe CAPRELSA, prescribers must:

- Read the Healthcare Provider (HCP) Letter; review HCP Education Pamphlet or HCP REMS Education Slide Set; and the CAPRELSA full Prescribing Information
- Complete the Prescriber Training Program (online or by phone)
- Complete the Prescriber Enrollment Form

To ENROLL, visit www.caprelsarems.com or call 1-800-236-9933.

To increase awareness of QT prolongation, Torsades de pointes and sudden death and the requirement for prescribers to enroll, please share this communication with the members of your society. We would ask that you also provide a link to the CAPRELSA REMS website at www.CAPRELSArem.com when disseminating this information to your members.

Please see the enclosed **HCP Education Pamphlet** that outlines the risk of QT prolongation, Torsades de pointes and sudden death associated with CAPRELSA.

This is not a complete list of all the Warnings and Precautions of CAPRELSA. Please see the enclosed full Prescribing Information for CAPRELSA.

Sincerely,

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