Roche

Pharmaceuticals

IMPORTANT NOTICE

STERILE FUDR
(floxuridine)

FOR INTRA-ARTERIAL INFUSION ONLY

January 24, 2000

Dear Doctor:

The supply of Sterile FUDR (floxuridine), currently approved and manufactured in the United States, is no longer available and will not be available for the foreseeable future due to manufacturing issues. You should take this information into consideration in any future prescribing decisions.

In order for patients to maintain access to FUDR during this emergency, we have reached an agreement with the Food and Drug Administration (FDA) to make a limited supply of FUDR, which cannot be guaranteed to be sterile, available for use as an investigational drug under the provisions of an Emergency Investigational New Drug Application (Emergency IND). Non-sterile FUDR will be made available under this program for as long as this limited supply lasts.

As a result of this situation, we have engaged the services of PPD Inc., a contract research organization (CRO), to guide physicians who may be interested in enrolling patients in this Emergency IND. Please call Mr. Darren Hart of PPD Inc. at 1-888-320-9383 between the hours of 7 a.m. and 9 p.m. (EST) to receive additional information or to make a request for this product. PPD has assigned a team of professionals on behalf of Roche to assist you

Roche is fully committed and working diligently to resolve this issue and will keep you apprised of changes in this situation. We sincerely regret any resulting difficulties caused to you or your patients during this period. We have enclosed complete product information on FUDR for your review.

Sincerely,

Alain Thibault, MD
Medical Director, Oncology

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