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by the Seton Network Medical Executive Committee.*

DRUG ALERT: Xigris [drotrecogin alfa (activated)] Withdrawn from Market by Eli Lilly

Effective immediately: Eli Lilly and Co. withdrew its sepsis drug Xigris [**drotrecogin alfa** (activated)] from all markets after the product failed to improve survival in a recently completed clinical trial (PROWESS-SHOCK trial).

Results of the 1,696-patient study showed Xigris did not meet the primary goal of a statistically significant reduction in deaths from any cause over a 28-day period in patients with septic shock (26.4 percent of patients receiving Xigris died compared to 24.2 percent receiving placebo), a difference that was not deemed statistically significant.

While there were no new safety findings (severe and serious bleeding), the study failed to demonstrate that Xigris improved patient survival, which called into question the benefit-risk profile of Xigris and its continued use.

Based on the results of this study, the FDA has recommended that new patients should not be started on Xigris and treatment of patients on the agent should be stopped immediately.

Accordingly, Seton Healthcare Family will adopt the FDA recommendations and remove Xigris from the Seton drug formulary, effective immediately. All remaining product will be returned to the supplier.

Thank you,

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Seton Healthcare Family