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April 21, 2005

Re: Discontinuation of Study F1K-MC-EVBP, *Investigation of the Efficacy and Safety of Drotrecogin Alfa (Activated) in Pediatric Severe Sepsis*

Dear Healthcare Professional,

I am writing to inform you that Eli Lilly and Company (Lilly) recently stopped enrollment in study EVBP, a randomized, double-blind, placebo-controlled trial of Xigris® [drotrecogin alfa (activated)] in pediatric patients with severe sepsis. Xigris is not indicated for use in pediatric severe sepsis.

The study's external, independent Data Monitoring Committee (DMC) recommended that the trial be stopped for futility after a planned interim analysis showed that Xigris was highly unlikely to show an improvement over placebo in the primary endpoint of "Composite Time to Complete Organ Failure Resolution" over 14 days.

The DMC also noted a numerical increase in the rate of central nervous system (CNS) bleeding in the Xigris versus the placebo group. Over the infusion period (study days 0-6) the number of patients experiencing an intracranial hemorrhage event was 4 versus 1 for the overall population (Xigris vs. placebo), with 3 of the 4 events in the Xigris group occurring in patients aged 60 days or less. Mortality, the rate of serious adverse events, overall serious bleeding events, and major amputations appeared to be similar in the Xigris and placebo groups. The main findings of the interim analysis are summarized in the following table:

	Xigris N=201 n (%)*	Placebo N=198 n (%)*
CTCOFRS (Composite Time to Complete Organ Failure Resolution), mean days ± standard deviation	9.7±5.0	9.8 ±5.1
28-day all-cause mortality	34 (17)	36 (18)
Deaths attributed to hemorrhage by investigator	1 (0.5)	5 (2)
Intracranial hemorrhage (ICH)		
Days 0-6 (infusion period)	4 (2)	1 (0.5)
Days 0-28 (entire study period)	8 (4)	5 (2)
Serious Adverse Events		
Days 0-6 (infusion period)	21 (10)	23 (12)
Days 0-28 (entire study period)	35 (17)	40 (20)
Serious Bleeding Events		
Days 0-6 (infusion period)	8 (4)	7 (4)
Days 0-28 (entire study period)	13 (6)	14 (7)

	Xigris N=201 n (%)*	Placebo N=198 n (%)*
At least one ICH event OR died during 28-day study period.	39 (19)	38 (19)
Major Amputations	4 (2%)	6 (3%)

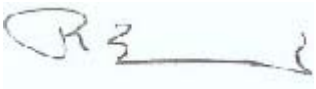
*Applies to all outcomes except CTCOFRS, which is reported as mean days ± standard deviation.

Data collection in study EVBP is ongoing. All patients enrolled will be followed for the complete 28-day study period. Full results of the data will be available in the latter part of 2005 and publicly presented as soon as possible.

Lilly is committed to ensuring that Xigris is used as safely and effectively as possible and to providing you with the most current product information. You can assist us with monitoring the safety of Xigris by reporting adverse events to the Lilly Answer Center at 1-800-LILLYRx (1-800-545-5979). Alternatively, adverse events may be reported to the FDA's MedWatch reporting system (phone: 1-800-FDA-1088, facsimile: 1-800-FDA-0178, or website: www.fda.gov/medwatch).

For reference, a copy of the prescribing information for Xigris is enclosed.

Sincerely,



Paul Eisenberg, MD
Vice President, Global Product Safety