Bayer HealthCare Media Statement

Bayer Reports Findings of Trasylol Independent Investigation

Company outlines corrective actions it has undertaken

Leverkusen, Germany and West Haven, Connecticut, USA. Today, Bayer HealthCare reported findings of Mr. William Taylor's independent investigation on the i3 Drug Safety observational study on Trasylol® (aprotinin injection) to the U.S. Food and Drug Administration (FDA) and other relevant regulatory authorities and also conveyed actions the company has taken to ensure that this sort of mistake is never again repeated. Mr. Taylor's full report and information regarding enhanced company practices and procedures have been posted on company websites.

Mr. Taylor, a partner with Zuckerman Spaeder LLP, is the independent counsel retained by Bayer[1] to investigate events surrounding the company's failure to inform the FDA that preliminary results from the i3 Drug Safety study on Trasylol had been received prior to the September 21, 2006 FDA Advisory Committee Meeting on Trasylol.

Among its findings, Mr. Taylor's independent investigation confirmed the timing of key events and conclusions regarding the roles, responsibilities and actions of Bayer employees that the company had reached in its own internal investigation and communicated to health authorities and the public at that time.

Mr. Taylor's Findings

Mr. Taylor's report confirmed that:

Only two Bayer employees from Bayer's Global Drug Safety Office in Germany had access to and were aware of the receipt by Bayer of the preliminary results from i3 Drug Safety prior to the September 21st FDA Advisory Committee meeting. These two individuals did not immediately disclose this information because they had significant questions about the study's methodology and analyses. They articulated these concerns in written questions to i3 on September 18, and when they did not receive responses before the Advisory Committee meeting they considered disclosure to be scientifically premature. While from a purely scientific perspective their decision may be understandable, under the circumstances of the pending FDA Advisory Committee, Bayer views their decision as a serious error of judgment. No other Bayer employees or any

[1]On October 13, 2006, Fred F. Fielding from the law firm Wiley Rein & Fielding LLP was retained to conduct the investigation. On Mr. Fielding's appointment as Chief White House counsel on January 8, 2007, Mr. Taylor was retained on February 7, 2007 and has conducted the investigation.

of the external consultants who supported Bayer at the Advisory Committee Meeting knew that the preliminary report from i3 Drug Safety had been received.

Bayer management preparing for the Advisory Committee meeting agreed and intended that the company should and would report the existence of the study to FDA in advance of the meeting, and, indeed, Bayer had an internal policy of transparency with the FDA on these issues.

Formal functional responsibility for this communication rested with Bayer's Global Regulatory Affairs department in the U.S., but, unfortunately, the information that the i3 Drug Safety study was underway was never conveyed. This failure was not motivated by any intent to conceal the existence of the study but was regrettable human error.

Mr. Taylor's full report of the Trasylol investigation can be found on the following Bayer web sites: www.trasylol.com, www.pharma.bayer.com, www.bayerscheringpharma.de/trasylol/en, and www.bayerhealthcare.com/trasylol/en

Bayer's Actions

In response to these events, Mr. Taylor's report, and in conjunction with the integration of Schering AG, Berlin, into the Bayer HealthCare pharmaceuticals business, Bayer has undertaken a thorough analysis of all of the company's drug safety and monitoring procedures. Based on the combined expertise of both organizations, Mr. Taylor's report, and lessons learned from this experience, we have strengthened a variety of already strong structures and rigorous processes.

In particular, Bayer has made changes in the responsibilities of its Protocol Review Committee – a unit whose structured processes play a critical role in ensuring that the mistakes and omissions that occurred in management of the i3 Drug Safety Study are not repeated. Responsible for evaluation and approval of the protocols for any clinical study sponsored or commissioned by Bayer's Pharma Business, the Protocol Review Committee's oversight will explicitly extend to company-sponsored or co-development studies in six categories including pharmacoepidemiological studies such as the i3 Drug Safety study.

Specific changes have also been made regarding commissioning and management of pharmacoepidemiology studies relating to potential safety or efficacy issues concerning BSP products. When developing protocols for these studies we will add new checks and balances including guidelines that organizations conducting these studies for Bayer notify a designated individual in Bayer's regulatory organization when study results are available as well as notifying the study sponsors. Additionally, once the PRC has approved the protocol for such a safety and efficacy related pharmacoepidemiology study, the company's Global Safety Committee will be notified and will decide on appropriate monitoring and reporting procedures.

A document briefly describing the respective roles of key committees in Bayer's drug safety and monitoring organization can be found on the following Bayer web sites: www.trasylol.com, www.pharma.bayer.com, www.bayerscheringpharma.de/trasylol/en, www.bayerhealthcare.com/trasylol/en

In Conclusion:

Bayer's goal in managing this situation has been to ascertain the facts, identify inconsistencies and deficiencies in our processes and correct these promptly. As part of that effort we have also reinforced and communicated to employees our commitment to complete and candid communications and ongoing dialog with regulatory agencies concerning the safety and efficacy of our products. With the changes made in our processes and renewed management focus and discipline, Bayer is confident that errors of this sort will not again occur.

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