

Trade/Business/Medical press

7<sup>th</sup> of August 2006

AstraZeneca K.K.  
Shionogi & Co., Ltd.

**Re: Crestor<sup>®</sup> for the treatment of hypercholesterolemia**  
**- The analysis from the interim report of post-marketing surveillance submitted**  
**to the regulatory authority -**

AstraZeneca K.K. (President: Masuhiro Kato, hereinafter "AZKK") and Shionogi & Co., Ltd. (President: Motozo Shiono, hereinafter "Shionogi") have submitted the interim report of post-marketing surveillance being conducted since its launch last April to the Pharmaceuticals and Medical Devices Agency. The interim analysis has confirmed that the safety profile of Crestor<sup>®</sup> is in line with the overseas data.

Crestor<sup>®</sup> was approved using clinical data from more than 10,000 patients, including Japanese patients, and the safety profile of Crestor<sup>®</sup> has been confirmed to be comparable with other marketed statins. This is also supported by overseas post-marketing surveillance data.

In launching Crestor<sup>®</sup>, AZKK and Shionogi placed priority on patient safety, and AZKK and Shionogi implemented Japan's first proactive "Pharmacovigilance plan" in line with the International Clinical Harmonization E2E guideline.

The interim analysis with more than 3,500 patients has confirmed the safety profile of Crestor<sup>®</sup> in the Japanese population. In addition, it has demonstrated that the Crestor<sup>®</sup> is effective at lowering LDL-cholesterol with or without previous medication.

With an emphasis on patient safety, AZKK and Shionogi have been focusing on the post-marketing surveillance with limited promotion, and while the companies plan to step up their promotional activities in late September, they will continue to be vigilant on safety following the revised Pharmacovigilance plan.

AZKK and Shionogi will continue to work closely together with a shared vision of what will be best for Crestor<sup>®</sup> from a long-term perspective, and will also continue to share in our commitment of developing Crestor<sup>®</sup> as a medicine which brings true value to hyperlipidemia patients.

ends