Press release, 28 May 2009

Positive study supporting a potential once-daily nasal antihistamine

In October 2008, the US Food and Drug Administration (FDA) accepted the New Drug Application (NDA) for the newly formulated higher strength azelastine nasal spray as complete for substantive review after initial evaluation.

This NDA contained data on six phase III studies and a long-term safety study, involving more than 1,600 patients in total. In these clinical studies, the product demonstrated improvement in nasal symptom relief scores in patients with seasonal and perennial allergic rhinitis, and was well tolerated.

Parallel to FDA's review process, Meda initiated a seventh phase III study. This study has now been completed and the results support a potential claim for a once-daily administration. Meda has decided to add this study to the submitted NDA. In response, FDA has requested three additional months to review this new information. Therefore, Meda anticipates a formal response on this NDA during September 2009.

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