Ped-5 (Protocol 93CE16-0623): A 12-Week, Open Label, Multicenter Study of the Safety of Cetirizine Syrup in the Treatment of Perennial Allergic Rhinitis in Children 6 to 11 Years of Age

The purpose of this study was to evaluate the safety of cetirizine 10 mg Q.A.M. in children 6 to 11 years of age with perennial allergic rhinitis during a 12-week treatment period.

This was an open-label, multicenter study of cetirizine 10 mg administered each morning before breakfast for a period of 12 weeks. Rescue decongestant (Sudafed liquid) was to be administered Q 4-6 hours, not to exceed 4 doses in 24 hours, in the event of unrelieved nasal congestion during the course of the study in addition to the study medication, unless medically contraindicated. Efficacy was assessed by the rating of signs and symptoms of allergic rhinitis, including sneezing, runny nose/post nasal drip, itchy eyes, itchy nose, mouth, and throat, red, teary eyes or swollen eyelids, and stuffy nose. These assessments were made by both the patients (parent and child) and investigator on a four-point severity scale ranging from 0 (none) to 3 (severe). Safety was assessed by laboratory evaluations and adverse experience monitoring. In addition, the investigator made global efficacy and safety evaluations in consultation with the patient and parent. Global efficacy was rated on a four-point scale ranging from 0 (ineffective) to 3 (extremely effective). Global safety was rated on a four-point severity scale that ranged from 0 (poor) to 3 (excellent).

Safety data from Ped-5 are presented in Sections D.3, D.5.c, D.6.c, and D.7.a of this safety update.