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## 2. SYNOPSIS

Both Study 20120178 and Study 20130255 each had a clinical home use (CHU) substudy that assessed users' ability to administer a full dose of AMG 334 140 mg in home use, using either 2 prefilled syringes or 2 prefilled autoinjector/pens. Each substudy was 12 weeks in duration, not including the screening period. A total of 136 subjects were enrolled in the studies and received at least 1 dose of investigational product. The majority (> 90%) of the subjects successfully self-administered 2 full doses of AMG 334 140 mg at home. The results were consistent across the individual study, age, and sex subgroups. Most treatment-emergent adverse events reported during the CHU substudies were grade 1 or grade 2. No subjects had fatal or treatment-emergent serious adverse events. None of the adverse events led to investigational product withdrawal. Overall, the safety results were consistent with the parent studies and other studies of AMG 334 and did not identify any new risks.

Approved