- This was a Phase I, randomized, double-blind, parallel, nested crossover thorough QT study that investigated the effect of treatment with albiglutide 30 or 50 mg SC injections given weekly over 6 weeks on cardiac repolarization (the QTc interval) in healthy male and female subjects; moxifloxacin (400 mg), a positive control, or moxifloxacin placebo was given on Days –1 and 40 in a nested crossover design to demonstrate the ability of the study to detect small QTc changes.
- Demographics were generally similar between albiglutide and placebo subjects. A total of 174 subjects were randomized, of whom 85 were enrolled in the albiglutide group and 89 in the placebo/moxifloxacin group, with a mean age of 29.5 years (range 18–45 years) and a mean BMI of 25.2 kg/m^2 (range 19.3–30.0 kg/m^2).
- Mean change-from-baseline QTcI (ΔQTcI) on Day 4 after a single dose of albiglutide 30 mg and on Day 39 after repeat dosing with albiglutide 50 mg once weekly was similar to the placebo response. The placebo-corrected ΔQTcI (ΔΔQTcI) on both albiglutide doses was small with the largest ΔΔQTcI of 1.1 msec (upper bound of 90% CI: 3.8 msec) on Day 4 and –0.6 msec (upper bound of CI: 1.8 msec) on Day 39. Concentration/QTc analysis revealed a negative relationship between albiglutide plasma concentrations and ΔΔQTcI, thereby demonstrating that albiglutide will not cause QTc prolongation at higher plasma levels.
- Moxifloxacin caused the largest mean effect on ΔΔQTcI of 10.9 msec and the lower bound of the CI was above 5 msec at all preselected timepoints, thereby demonstrating assay sensitivity.
- Albiglutide at doses up to 50 mg in healthy subjects did not prolong the QTc interval, was well-tolerated, and there were no clinically relevant differences in treatment safety data between albiglutide and placebo.

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