Enrolled (n=283)

Did not enter lead-in* (n=117)

Entered lead-in (n=166)

Excluded (n=6)
- Withdrawal of consent (n=3)
- Poor compliance (n=1)
- Adverse event† (n=1) or elevated liver enzymes‡ (n=1)

Randomized (n=160)

Saxagliptin 2.5 mg BID (n=74)
- Took ≥1 dose (n=74)

Lost to follow-up (n=1)
Discontinued intervention (n=7)
- Lack of efficacy (n=2)
- Withdrawal of consent (n=1)
- Poor/noncompliance (n=2)
- No longer met study criteria (n=2)

Completed week 12 (n=66, 89.2%)

Placebo (n=86)
- Took ≥1 dose (n=86)

Lost to follow-up (n=2)
Discontinued intervention (n=6)
- Lack of efficacy (n=2)
- Withdrawal of consent (n=2)
- Poor/noncompliance (n=2)

Completed week 12 (n=78, 90.7%)