Phase III, randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of teneligliptin monotherapy in Chinese patients with type 2 diabetes mellitus (T2DM) inadequately controlled with diet and exercise

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- This multicenter, randomized, double-blind, placebo-controlled, parallel-group study, carried out at 42 sites, enrolled T2DM with glycosylated hemoglobin 7.0 to <10.0% and fasting blood glucose <270 mg/dL.
- Patients were randomly assigned, in a 1:1 ratio, to treatment with 20 mg teneligliptin or a placebo (n = 127, each) administered orally once daily before breakfast for 24 weeks.
- Change in glycosylated hemoglobin from baseline to week 24 was -0.95% with teneligliptin versus -0.14% with a placebo.
- Change in fasting blood glucose from baseline to week 24 was -21.9 mg/dL with teneligliptin versus -1.4 mg/dL with a placebo.

At 24 weeks, teneligliptin was generally well tolerated and effective in T2DM patients inadequately controlled with diet and exercise.