

Dong-A Pharma gets positive trial results for Evogliptin

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Singapore: South Korea's Dong-A Pharmaceutical announced positive top-line results from its phase II clinical trial of DPP-4 inhibitor, Evogliptin (DA-1229).

The multi-center phase II clinical trial conducted in Korea was a randomized, double-blind, placebo-controlled, therapeutic exploratory clinical study to investigate efficacy and safety of Evogliptin. A total of 157 patients with type 2 diabetes who had inadequate glycaemic control on diet and exercise were administered with either placebo or one of the three doses of Evogliptin (2.5, 5, 10 mg) once daily for 12 weeks.

Evogliptin met primary endpoint at all dose groups by significantly lowering HbA1c level from baseline compared to placebo group. Evogliptin was proven to be safe and well tolerated at all dose groups with no severe ADRs found in the phase II clinical trial. There were no statistically significant differences in the incidence rates of ADRs between Evogliptin treatment groups and placebo group. Furthermore, no pancreatitis-related AEs were reported in this trial.

Collectively, the dose regimen of 5 mg once daily was selected for phase III clinical trials. This is an expected result because Evogliptin was already found to be highly potent in the previous studies.

Dong-A pharmaceutical signed license agreements of Evogliptin with Chinese and Indian pharmaceutical companies last year that granted the rights of Evogliptin in the territory of China and India and Nepal, respectively. The company plans to initiate phase III clinical trials in the first half of this year using 5 mg dose of Evogliptin as monotherapy and combination therapy with metformin, and expects its launch in 2016 in Korea.