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Press release

Mitsubishi Tanabe Pharma Corporation

Positive Phase 3 Results of Canagliflozin in Japanese Patients with Type 2 Diabetes at American Diabetes Association

Osaka, Japan, June 16, 2014 --- Mitsubishi Tanabe Pharma Corporation (President & Representative Director, CEO: Michihiro Tsuchiya) announced today that the results of a Phase 3 clinical study of a sodium glucose co-transporter 2 (SGLT2) inhibitor, canagliflozin (CANA) being aimed at Japanese patients with type 2 diabetes were presented at 74th Scientific Sessions of American Diabetes Association, being held in San Francisco, USA from June 13 to 17 2014 (abstract number: 1032-P). The results show statistically significant and clinically meaningful improvement of glycemic control in type 2 diabetes patients.

Outline of Study Methods

Purpose	To evaluate the efficacy and safety of CANA monotherapy for a period of 24 weeks in Japanese patients with type 2 diabetes
Patients	Japanese patients with type 2 diabetes who had inadequate glycemic control on the treatment with diet and exercise
Study Design	Multicenter, randomized, placebo(PBO)-controlled, double-blind
Number of subjects	272
Primary endpoint	Change from baseline in HbA1c levels at Week 24

Summary of results

Efficacy	• CANA demonstrated a statistically significant reduction in HbA1c compared to PBO at Week 24. (change from baseline in HbA1c at Week 24 relative to placebo of -1.03%, -1.05% for CANA 100 mg and 200 mg, respectively) • In 75 g OGTT, statistically significant reductions in the 2h-post-challenge glucose levels relative to placebo from baseline to Week 24 of -84.4 mg/dl and -78.5 mg/dl were observed with CANA 100 mg and 200 mg, respectively. • Statistically significant improvements in HOMA2-%B as an index for beta cell function were observed in both CANA groups. • At Week 24, CANA significantly reduced body weight (BW) and systolic blood pressure versus PBO.
Safety	• Overall incidences of adverse event in CANA 100 mg, 200 mg and PBO were 66%, 62% and 59%, respectively. CANA 100 mg and 200 mg were associated with higher rates in genital mycotic infections in women, but none led to discontinuation. Incidences of symptomatic hypoglycaemia were low with no episode of severe hypoglycaemia. • CANA 100 mg and 200 mg, compared to PBO improved glycemic control, led to reductions in BW and were generally well tolerated.

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