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Investigational New Class of Oral Medication for Patients with Type 2 Diabetes, Sitagliptin (a DPP-4 inhibitor), Begins Phase III Clinical Trials in Japan

Phase III clinical trials for an investigational new class of oral medication for patients with type 2 diabetes, sitagliptin (Development Code: MK-0431/ONO-5435), have begun in Japan. Sitagliptin, developed by Merck (Merck & Co., Inc., Whitehouse Station, New Jersey, USA) is a member of a potentially new class of oral drugs (dipeptidyl peptidase-4 [DPP-4] inhibitors) that enhances the body's own ability to lower blood sugar (glucose) when it is elevated. The mechanism of action of DPP-4 inhibitors is distinct from that of any currently available class of glucose lowering agents. Phase II clinical trials for this medicine were conducted by Banyu. From Phase III onward, sitagliptin will be jointly developed by Banyu and Ono in accordance with the licensing agreement executed between Merck and Ono in 2004.

Sitagliptin is a potent and highly selective DPP-4 inhibitor. DPP-4 inhibitors work by enhancing a natural body process that lowers blood sugar, the incretin system. When blood sugar is elevated, incretins work in two ways to help the body regulate high blood sugar levels: they trigger the pancreas to increase insulin and signal the liver to stop producing glucose. DPP-4 inhibitors enhance the body's own ability to control blood sugar levels by increasing the active levels of these incretin hormones in the body, helping to decrease blood sugar levels in patients with type 2 diabetes. In controlled international clinical development studies sitagliptin demonstrated substantial reduction in blood sugar (glucose levels) and was not associated with weight gain from baseline. The incidence of hypoglycaemia (when blood sugar becomes too low) in theses studies was similar to placebo.

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