

TWi Biotechnology completes phase II study of AC-201

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Singapore: TWi Biotechnology, the wholly owned subsidiary of Taiwan-based TWi Pharmaceuticals, has completed a multinational phase II dose-ranging study of AC-201, an orally available IL-1 Beta modulator, in 259 patients with type II diabetes uncontrolled on up to three oral medications. In the intent-to-treat population, AC-201 showed placebo-corrected reductions in HbA1c of 0.20 percent, 0.29 percent, and 0.35 percent after 24 weeks of treatment in the three tested dose groups of 25 mg, 50 mg, and 75mg twice daily (b.i.d), respectively.

The clinical trial was conducted in the US, where 150 patients were enrolled in 13 sites, and Taiwan, where 109 patients were enrolled in eight sites.

"We are pleased to see AC-201 once again demonstrated a good potential to be a treatment for patients with type II diabetes; the data from patients in the US are especially encouraging," said Dr Calvin Chih-Kuang Chen, acting president of TWi Pharmaceuticals. Referencing AC-201's unique mode of action that targets the inflammation pathway associated with both impaired beta-cell function and insulin resistance, Dr Dee Pei, professor of Medicine, Fu Jen Catholic University and chief of Internal Medicine, Cardinal Tien Hospital, Taipei, Taiwan, said, "I am mostly impressed by AC-201's ability to reduce HbA1c levels in those very difficult to treat patients. AC-201 could be a very useful tool when combinations of drugs are required to achieve successful control of blood sugar in certain type II diabetic patients."

AC-201 is the only orally available small molecule in development which modulates the intracellular synthesis of the cytokine IL-1Beta. Inhibition of IL-1Beta signaling has been demonstrated to be effective in treating a variety of inflammatory diseases including arthritis, diabetic nephropathy (DN) and diabetic mellitus (DM).