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Singapore: Taiwan based TWi Pharmaceuticals has received US FDA and Taiwan FDA approval of a protocol for a Phase II clinical trial of its AC-201 controlled-release (CR) tablets for the indications of high blood uric acid level and gout.

AC-201 is a first-in-class, small molecule which has shown the ability to inhibit the production and activity of caspase-1 and the cytokine Interleukin-1Beta (IL-1Beta), and to down-regulate IL-1Beta receptors. Inhibition of IL-1Beta signaling has been demonstrated to be effective in treating a variety of diseases including arthritis, gout, and diabetes mellitus (DM). The active ingredient of AC-201 has been approved for treating patients with chronic rheumatic diseases in France and subsequently in other EU and Middle Eastern countries such as Spain and Italy since the mid-1990s.

The company is now looking to start to enroll patients for the Phase II clinical trial.

"We are very pleased with the approval of the Phase II clinical trial protocol for AC-201 CR." said Dr Calvin C Chen, president, TWi Biotechnology. "The purpose of this Phase II trial is to determine the effectiveness of AC-201 CR in reducing uric acid levels in the blood of gout patients. This is a joint effort by TWi Biotech and its parent company, TWi Pharma, in applying TWi Pharma's controlled-release drug delivery platform. We developed a safer and higher bioavailability formulation than the original instant-release formulations. The upcoming trial will assess the efficacy and safety of this new formulation."