

Headlines Advinus' GK-activator Achieves Early POC for Diabetes

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Description

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Partnership Dialog Actively Underway

Advinus Therapeutics, a research-based pharmaceutical company founded by globally experienced industry executives and promoted by the TATA Group, announced that it has successfully completed a 14-day POC study in 60 Type II diabetic patients on its lead molecule, GKM-001, a glucokinase activator. The results of the trial show effective glucose lowering across all doses tested without any incidence of hypoglycemia or any other clinically relevant adverse events.

The clinical trials on GKM-001 validate the company's pre-clinical hypothesis that a liver selective Glucokinase activator would not cause hypoglycemia (very low blood sugar), while showing robust efficacy.

"GKM-001 is differentiated from most other GK molecules that are in development, or have been discontinued, due to its novel liver selective mechanism of action. GKM-001 has a prolonged pharmacological effect and a half-life that should support a once a day dosing as both mono and combination therapy." said Dr. Rashmi Barbhaiya, MD & CEO, Advinus Therapeutics. He added that Advinus is actively exploring partnership options to expedite further development and global marketing of GKM-001.

GKM-001 belongs to a novel class of molecules for treatment of type II diabetes. It is an activator of Glucokinase (GK), a glucose-sensing enzyme found mainly in the liver and pancreas. Being liver selective, GKM-001 mostly activates GK in the liver and not in pancreas, which is its key differentiation from most competitor molecules that activate GK in pancreas as well. The resulting increase in insulin secretion creates a potential for hypoglycemia—a risk GKM-001 is designed to avoid. Advinus has the composition of matter patent on GKM-001 for all major markets globally. Both the Single Ascending Dose data, in healthy and type II diabetics, and the Multiple Ascending Dose Study in Type II diabetics has shown that the molecule shows effective glucose lowering in a dose dependent manner and has excellent safety and tolerability profile over a 40-fold dose range. The pharmacokinetic properties of the molecule support once a day dosing. GKM-001 has the potential to be "First-in-Class" drug to address this large, growing and yet poorly addressed market.

Advinus also has identified a clinical candidate as a back-up to GKM-001, which is structurally different. In its portfolio, the company has a growing pipeline for COPD, sickle cell disease, inflammatory bowel disease, type 2 diabetes, acute and chronic pain and rheumatoid arthritis in various stages of late discovery and pre-clinical development.

About the Diabetes Market:

The present 300 million diabetics population is estimated to jump to 450 million by 2030 worldwide. A large proportion of these patients are poorly controlled despite multiple therapies. Total sales of diabetic prescription products were \$32 billion in 2010.