Headlines	Advinus discovers novel molecule for treatment of diabetes, completes Phase 1 Single Ascending Dose study
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Description

Advinus Therapeutics, the research-based pharmaceutical company promoted by the TATA Group has discovered a novel molecule for the treatment of type II diabetes - GKM -001. The molecule is an activator of glucokinase; an enzyme that regulates glucose balance and insulin secretion in the body.

GKM-001 is the completely indigenously developed molecule and the initial clinical trials have shown excellent results for both safety and efficacy.

"Considering past failures of other companies on this target, our discovery program primarily focused on identifying a molecule that would be efficacious without causing hypoglycemia. The Phase I data indicate that GKM - 001 is a liver selective molecule that has overcome the biggest clinical challenge of hypoglycemia. GKM-001 is differentiated from most other GK molecules in development due to this novel mechanism of action," said Dr. Rashmi Barbhaiya, MD & CEO, Advinus Therapeutics.

"GKM-001 is 100% Indian. Advinus"s team in Pune discovered the molecule and entire preclinical development was carried out at our center in Bangalore. The IND (Investigational New Drug) application was filed with the DGCI for approval to initiate Clinical trials in India within 34 months of initiation of the discovery program. Subsequent to the approval of the IND, we have completed the Phase 1 Single Ascending Dose study in India within two months," he added.

GKM-001 is a novel molecule for the treatment of type II diabetes. It is the first Glucokinase modulator discovered and developed in India and has potential to be both first or best in class. The success in discovering GKM-001 is attributed to the science driven efforts in breaking the conventional mold for selection of a drug candidate.

Advinus has composition of matter patent on the molecule for all major markets globally.

Glucokinase as a class of target is considered to be novel as currently there is no product in the market or in late clinical trials. The strategy for early clinical development revolved around assessing safety (particularly hypoglycemia) and early assessment of therapeutic activity (glucose lowering and other biomarkers) in type II diabetics. The Phase I data, in both healthy and type II diabetics, shows excellent safety and tolerability over a 40-fold dose range and desirable pharmacokinetic properties consistent with "once a day" dosing. The next wave of clinical studies planned continues on this strategy of early testing in type II diabetics.

Right behind the lead candidate GKM-001, Advinus has a rich pipeline of back up compounds on the same target. These include several structurally different compounds with diverse potency, unique pharmacology and tissue selectivity. Having discovered the molecule with early indication of wide safety margins, desired efficacy and pharmacokinetic profiles, the company is now seeks to out-license GKM-001 and its discovery portfolio.

In 2010, it is estimated that there are about 300 million adult (between 20 and 79 years) diabetics worldwide. It is also expected that by 2030 about 450 million people worldwide would be diabetics. Type II diabetes mellitus constitutes about 85% to 95% of all diabetes cases in high-income countries and accounts for possibly a higher percentage in low to mid income countries. In India itself it is estimated that there are about 51 million diabetics in 2010 and this number in all likelihood will go up to 80 million by 2030.

Note: This news appeared in leading Business Newspapers like Business Line, Financial Express, Business Standard, on 07th Sep, 2010. It also appeared on various online sources