

Advinus Team Discovers Novel Molecule for Treatment of Diabetes

Advinus Therapeutics, a research-based pharmaceutical company founded by leading global pharmaceutical executives, and promoted by the Tata Group announced the discovery of 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; a side-effect associated with most compounds developed for this target. Recently completed phase I data indicate that Advinus’ 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 Barbhaya, managing director & CEO, Advinus Therapeutics.

He further added “We are very proud that GKM-001 is 100 percent Indian. Advinus’s discovery 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 I single ascending dose study in India, within two months.”

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 Advinus laboratories, and “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.

About Advinus Therapeutics

Advinus Therapeutics is a research-based Pharmaceutical Company founded by leading global pharmaceutical executives and promoted by the TATA Group. The company is the first of its kind in India to offer end-to-end development services to the global Pharma, Agro and Biotech industries and at the same time creating long-term value through internal and collaborative innovative Drug Discovery. ■



Contact Details:

Advinus Therapeutics Pvt. Ltd.

Address: Quantum Towers
Plot No 9, Rajiv Gandhi
Infotech Park,
Phase – I, Hinjewadi, India

Tel: +91 20 6653 9600

Fax: +91 20 66539620

URL: www.advinus.com