

New molecule for diabetes treatment found

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Advinus Therapeutics, a research-based pharmaceutical company promoted by the Tata Group, has announced the discovery of a novel molecule, GKM-001, for the treatment of type 2 diabetes. The molecule is an activator of glucokinase; an enzyme that regulates glucose balance and insulin

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

GKM-001 is a novel molecule for the treatment of type 2 diabetes. It is the first glucokinase modulator discovered and developed in India. 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 2 diabetics. The phase I data, in both healthy and type 2 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 2 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 now seeks to out-license GKM-001 and its discovery portfolio.

Max Neeman expands therapeutic trial

Max Neeman International, a full service clinical research organization headquartered in New Delhi, has expanded therapeutic-focused clinical trial services in India. Max Neeman has formed a world class team of medical device experts, specializing in carrying out cardiac device trials – therapeutic, diagnostic and surgical.

Along with prior experience in conducting device trials, the specialized Max Neeman team and services adds an enhanced level of company expertise, in conducting simple to complex device studies. Max Neeman has medical device operations and regulatory experience in various other device therapeutic areas as well, including central nervous system and ophthalmology.

India is emerging as a destination of choice for medical device development and conducting device trials, as the market for percutaneous coronary interventions has expanded. India's medical device market is currently valued 1000 \$7,672 or or \$1,672 or

Biocon, Teleradiology partner

Biocon, a leading biotechnology company in India, has entered into an agreement with Teleradiology Solutions, for getting teleradiology reporting services to Clinigene, its clinical research organization. Teleradiology Solution's quality-driven reporting process and technology platform benefits biotechnology and pharmaceutical companies; and it also eliminates delays in the completion of clinical trials, by optimizing the radiology reporting process.

Dr Kiran Mazumdar-Shaw, chairman and managing director of Biocon, said, "To achieve our main objective of accelerating clinical research, we rely on an adept mix of technology, experience and personal traits. Keeping in line with our mission, Teleradiology Solutions, was the partner of choice to meet our complex image analysis requirements. The signing of this agreement further endorses Bangalore as the hub of excellence, both in biotechnology as well as in high-end healthcare delivery to the world."

Dr Arjun Kalyanpur, managing director and chief radiologists, Teleradiology Solutions, said, "For pharmaceutical and biotechnology companies involved in drug development R&D, delays in the drug development cycle can be an issue of concern. These are, in part, related to delays in reporting of radiologic scans that are performed, to confirm that the patient under treatment has responded positively to the drug being evaluated in the clinical trial. The delays are, in turn, related to the worldwide shortage of radiologists, estimated to be as high as 20 percent in some studies."