BioSpectrum the business of Bio & Health Sciences

Successful completion of global phase I/II clinical trial for Galnobax

04 November 2015 | News | By BioSpectrum Bureau

Successful completion of global phase I/II clinical trial for Galnobax

Pune-based NovaLead Pharma, a drug discovery and development company, announced a potential breakthrough in the treatment of diabetic foot ulcers (DFU), which is a frequent complication of uncontrolled diabetes over a period of time.

The recently concluded global Phase I/II clinical trial of its repositioned investigational drug, Galnobax successfully met both primary and secondary end points for efficacy and safety.

The scientific challenge in this discovery can be understood by the fact that the last and the only USFDA approved drug for DFU came in 1997.

The gel can be self-administered at home without significant side-effects thus providing additional benefits to patients in terms of convenience and saving hospital costs

In this trial, Galnobax demonstrated significant benefit over placebo in terms of ability to close hard to heal DFUs in much shorter time, making it potentially the first small molecule drug for DFU.

In addition, the trial reported no side effects of any significance.

The data supports anticipated mechanism of action of Galnobax that it triggers the intrinsic wound healing processes impaired in diabetics.

According to the company's press release, in comparison to the published data of existing therapies like growth factors and skin grafts, Galnobax trial data is considerably superior in terms its wound closing ability as well as the time to heal.

That it is self-administrable, Galnobax is likely to save expenses for the patients and also ensure better compliance.

This innovation is noteworthy because Galnobax is a generic drug originally indicated for a cardiac condition, repositioned by NovaLead for DFU in a gel form for topical use.

Galnobax is discovered through NovaLead's proprietary technology platform which enables systematic approach for finding novel therapeutic indications for known drug molecules.

Using this platform NovaLead has generated a robust pipeline of which Galnobax is the first candidate in human trial.

Galnobax has already received patents in all regulated markets namely USA, EU and Japan as well as in emerging markets like India and China.

Further development of Galnobax is substantially de-risked as safety concerns are insignificant and the Phase I/II clinical trials demonstrate that its efficacy is significantly superior to placebo plus standard of care.

Galnobax has recently been adjudged as the Best Innovation in Healthcare in 2015 by DBT-BIRAC which is an initiative of the Department of Biotechnology, Government of India.

The company will be further developing the product through registration trial preferably along with a partner and will launch the drug in 2018.