Lupin Receives Approval For Conducting Phase II Trials For LLL-3348 (Desoris)

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Mumbai, 28 November 2005 : Lupin Ltd. announced today that it has received approval for conducting phase II clinical trials of its Investigation New Drug candidate LLL-3348 (Desoris) from the Drug Controller General of India (DCGI). Desoris is proposed for the treatment of moderate to severe chronic stable plaque-type psoriasis.

The most common form of psoriasis is plaque-psoriasis which is a chronic, immune-mediated disease, which can cause severe physical discomfort and have a significant impact on a person's quality of life. The disease manifests itself as lesions that are classically well circumscribed, circular, red papules or plaques with a grey or silvery-white, dry scale. Psoriasis can have a significant negative impact on the physical, emotional, and psychosocial well-being of affected patients. There are several treatment modalities available for psoriasis including phototherapy and systemic therapies, but most of these are associated with significant cutaneous and systemic adverse effects. The side effect profile of existing drug therapies itself leads to marked reduction in patient's compliance.

Speaking of the nod to go ahead for further clinical trials, Chairman Dr. DB Gupta stated that 'There is an imperative need of effective and safe drugs to be made available in the global pharmaceutical market for Psoriasis and we are very excited that the regulatory authorities found our data promising enough to give us permission for further trials'. The approval comes on Lupin's successful completion of the therapeutic evaluation and safety profiling of Desoris in a phase I single and multiple dose study in healthy volunteers. Desoris being an orally bioavailable and safe drug will now be evaluated for efficacy in patients in a phase II clinical trial by Lupin Ltd. spanning 10 sites across India, starting very shortly.

Desoris is a herbal aqueous extract of a single plant that has a novel mechanism of action and effectively modulates the cellular function leading to marked psoriatic lesion improvement without any toxic effects. The candidate has been developed conforming to guidelines laid down by the US FDA for botanicals as well as DCGI guidelines on new drug development. The project is being developed in collaboration with the CSIR's NMITLI program.

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