

## Oral treatment for Psoriasis soon

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There is no present cure for psoriasis, but there are a number of drugs and treatments that can relieve and control psoriasis, often for long periods of time.

Help will soon be at hand for people suffering from psoriasis. Lupin Laboratories has received the approval from the Drug Controller General of India (DCGI) for conducting Phase II clinical trials of its investigation new drug candidate LLL-3348 (Desoris). Desoris is a proposed treatment of moderate to severe chronic stable plaque-type psoriasis.

The approval has come on the company's successful completion of the therapeutic evaluation and safety profiling of Desoris in Phase I single and multiple dose study in healthy volunteers. The formulation being an orally bioavailable and safe drug, will now be evaluated for efficacy in patients in a Phase II clinical trial by the company spanning 10 sites across India, starting very shortly.

Speaking about the clearance for further clinical trials, Dr DB Gupta, chairman, Lupin, said that they are very excited that the regulatory authorities found out data promising enough to give permission for further trials.

Psoriasis is one of the most common dermatological diseases affecting around 2 percent of the world population. It is a chronic inflammatory skin disorder with most common areas affected being the joints like elbows, knees, gluteal cleft and scalp. Its cause and pathogenesis are not clearly understood. This disorder is recognized for its peculiar clinical symptoms

characterized by circumscribed red patches covered with white scales resulting in itchy flaky skin. It ranges from a few spots to large areas all over body. Although psoriasis manifests as a skin disorder, it is believed to be a disease of impaired or defective cell mediated immunity. Most importantly, no preventive/curative therapy exists for psoriasis except the symptomatic management. Hence there has been an impending need for effective and safe oral drugs in the global pharmaceutical market for this disease.

Based on the traditional knowledge, this project involving the development of a single plant based oral herbals formulation was initiated under the Council of Scientific and Industrial Research's (CSIR) New Millennium Indian Technology Leadership Initiative (NMITLI). NMITLI is a unique Indian public-private partnership to secure a leadership position in niche areas based on technology through "Team India" effort. Adopting the reverse pharmacology approach, the project is being led by Lupin Laboratories as the industry partner. The project network involves two institutional partners.

The drug candidate is an 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. Lupin has developed this product in the form of capsules. Extensive studies comprising fingerprinting, activity guided fractionation, efficacy studies, toxicology, safety pharmacology, pharmacokinetics and toxicokinetics had earlier helped the company in filing an Investigational New Drug (IND) application in December 2003, which was cleared in March 2004. Lupin then commenced the Phase I clinical trial for Desoris in September 2004 and successfully completed it. Based on animal data, the drug has been found to be efficacious and safe and animal pharmacokinetic data suggests that the botanical Desoris could be used once a day.

The candidate has been developed conforming to the guidelines laid down by the US FDA for botanicals as well as DCGI norms on new drug development. The estimated market for psoriasis therapeutics is around \$4 billion and the development will enable India to capture a significant part of the market.

Rolly Dureha

### Effective, safe anthrax vaccine can be grown in plants

Enough anthrax vaccine to inoculate everyone in the US could be grown inexpensively and safely with only one acre of tobacco plants, a University of Central Florida molecular biologist has found.

Mice immunized with a vaccine produced in UCF professor Henry Daniell's laboratory through the genetic engineering of tobacco plants survived lethal doses of anthrax administered later by National Institutes of Health researchers. The results of the NIH-funded study are featured in the December issue of the Infection and Immunity journal.

Daniell's research is a breakthrough in efforts to find a safe and effective method of producing large quantities of vaccine for anthrax, one of the top bioterrorism threats facing the US. The new production method also could help the government and health care providers avoid supply shortages, as one acre of plants can produce 360 million doses in a year.

Current production of the vaccine involves an expensive fermentation process that can cause harmful side effects such as inflammation, flu-like symptoms and rashes. This has prompted some people to refuse to be vaccinated.

Seeking a safer and more effective alternative, Daniell and his colleagues injected the vaccine gene into the chloroplast genome of tobacco cells, partly because those plants grow much faster than carrots, tomatoes and coffee. They grew the cells for several weeks in Daniell's laboratory. Tests showed the vaccine taken from the plants was just as potent as the one produced through fermentation but lacks the bacterial toxin that can cause harmful side effects.

Henry Daniell, professor at the Research College of Biomedical Sciences, injected the vaccine into mice to immunize them against anthrax and sent the mice to NIH labs, where they survived lethal doses of anthrax several times stronger than the amounts to which humans have been exposed.

The next step for the anthrax vaccine would involve a company working with NIH to conduct clinical trials. Human subjects would be injected only with the vaccine and not with anthrax itself, and scientists would then check the subjects' immunity levels. The vaccine later could be mass-produced and stockpiled for emergencies.

Daniell's work holds promise for treating other diseases, including diabetes and hepatitis, and improving vaccines for plague, cholera and other bioterrorism agents. He is developing a new technology that would enable vaccines to be administered orally and allow effective and less expensive treatments to be more accessible worldwide.

He also believes fruits and vegetables such as carrots and tomatoes are the keys to figuring out a way for people to take anthrax vaccines orally in capsules of dried plant cells that contain correct doses of the protective antigen.