



DermaTools Biotech GmbH selects new manufacturer of the active substance DermaPro® and thus creates the basis for the repeat of the phase III clinical trial

- DermaTools Biotech GmbH signs contracts for production by a new German manufacturer.
- Prerequisites for the repeat of the phase III clinical trial fulfilled.
- Production in cooperation with license partner Centaur for India makes progress.

Darmstadt, 22.04.2016 – The talks with renowned European manufacturers have been successfully concluded. The DermaTools Biotech GmbH has engaged a new German manufacturer for the production of the active substance DermaPro® and the finished drug form. The corresponding contracts have been signed subject to the necessary approvals from the regulatory authorities. These will be obtained during the technology transfer process. Thus, the new German manufacturer will produce the active substance and product needed for the repeat of the phase III trial in the diabetic foot indication, as well as the requirements for further European trials, and furthermore, be in a position to compensate for any demand peaks in India.

In the meantime, the DermaTools Biotech GmbH, together with Centaur Pharmaceuticals, the licensee for India, has completed all the prerequisites for a short term FDA and EU certification of the Centaur factory in Ambernath, and thus the manufacture of the active substance in their own facilities. The plant will be constructed in the coming weeks and must then also be approved by the regulatory authorities in India. Establishing the manufacture of the active substance DermaPro® in India will mean a considerable increase in the chances of a new drug approval in India.

Now that the reasons for the wrong active substance concentrations in the preceding diabetic foot phase III trial are known, these can be categorically excluded in future. With this knowledge, and the change of manufacturer, we are creating the conditions for the authorities to approve a repeat of the phase III trial.

Dr. Kaiser, the responsible director, commented: „We have now achieved all the prerequisites for the resumption of the clinical trials in Europe. We shall execute the technology transfer as quickly as possible so that the first batches for the repeat of the diabetic foot trial can be made available soon. Simultaneously, the application for this clinical trial will be submitted to the responsible authorities and then we can begin.“

PRESS RELEASE



CytoTools

This press release contains specific future-oriented statements. These reflect the opinion of CytoTools on the date of this release. The actual results achieved by CytoTools could substantially deviate from the future-oriented statements made. CytoTools is not obligated to update these future-oriented statements.

About CytoTools:

The **CytoTools AG**, previously CytoTools GmbH, is a technology holding and investment company which holds shares in its subsidiary companies in the pharmaceutical and medical products field: about 58 % of DermaTools Biotech GmbH (therapy field - dermatology, urology) and 42% of the CytoPharma GmbH (therapy field cardiovascular disease, cancer). The complete know-how is protected by corresponding basic patents which are maintained worldwide by CytoTools AG and it is transferred by the CytoTools AG to the associated companies in the form of worldwide exclusive licenses.

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