



CytoTools AG: Market authorization application submitted for DermaPro® in India

- License partner Centaur Pharmaceuticals expects market launch in the second half of 2014
- European phase III trial commences successfully with already more than 40 recruited patients

Darmstadt, 18th December 2013 – Centaur Pharmaceuticals, license partner of CytoTools AG in India, has submitted the market authorization application for DermaPro®, the wound healing agent, to the Indian authorities according to schedule. The drug, which will be called Woxheal® in India, will first be used for the indication diabetic foot (diabetic foot ulcer). Subsequently, the extension to additional indications is planned. The final step before the market launch has now been taken with the submission of the authorization documents.

The application submission is the result of a phase III clinical trial with over 300 patients and an outstanding healing rate of over 91 % which was completed successfully in June 2013. The percentage of completely closed wounds was corrected upwards in the final evaluation to 76 % (previously 71 %). CytoTools has already reported the details here in previous press releases. The past weeks have been spent particularly in compiling the required documentation for obtaining market authorization. This has now been presented to the Indian authorities. If all goes according to plan, Centaur Pharmaceuticals expects the authorization and the product launch in the second half of 2014.

Dr. Mark-Andre Freyberg, joint managing director of the CytoTools AG, explained: „We are delighted that Centaur has been successful in completing this extremely voluminous work in the relatively narrow timescale and that the complete documentation has been submitted to the authorities at the end of the year.“

In order to satisfy the expected large demand directly after authorization is obtained, the Indian license partner has already ordered 130,000 units of DermaPro® from CytoTools. Further production orders, which will all be processed in Germany, are to follow at the beginning of 2014. Dr. Freyberg commented: „We also see this as clear evidence for the high success probability of the authorization for the Indian market.“

PRESS RELEASE



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In Europe too, the clinical development of DermaPro® is making great progress: Further success can also be reported from the phase III clinical trial, planned for up to 300 patients, which is also being carried out for the diabetic foot indication.

Dr. Dirk Kaiser, joint managing director of the CytoTools AG, explained: „The trial has now begun in most of the European countries we are targeting. Of the planned 30 high profile clinical trial centers, 24 are already active and over 40 patients are now participating.“ Judging by the current development, CytoTools estimates that the last centers will also be able to begin their work in the first quarter of 2014.

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.

CytoTools AG, previously CytoTools GmbH, is a technology and holding company which holds the following shares in its subsidiaries which carry out product development in the pharmaceutical and medical products field: around 58% in DermaTools Biotech GmbH (therapy field dermatology, urology) and 46% in 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 transferred to the subsidiary companies in the form of exclusive licenses.

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