



CytoTools AG before important milestones:

Indian regulatory authorities recommend registration of DermaPro® and data from the phase III trial will be available in November

- After extensive meeting, Indian regulatory authorities recommend registration of DermaPro®
- Clinical phase III trial in Europe for diabetic foot indication shortly before unblinding and final evaluation

Darmstadt, 30th October 2015 – Consultations were held in an IND (Investigational New Drug) meeting with the Indian regulatory authorities in August on the wound healing agent DermaPro®, from CytoTools subsidiary DermaTools Biotech GmbH, for the diabetic foot indication. After the Indian partner, Centaur Pharmaceuticals had carried out the additional toxicological studies, started at the beginning of the year and completed in June, the results, which again confirm the excellent safety profile, were submitted to the authorities. At the meeting in August between Centaur and representatives of the authority Drug Controllers of India, in the presence of Dr. Kaiser CSO of the CytoTools AG, detailed discussions were held on the scientific background, the medical development, the active substance and the new completed medication itself. Particularly the editorial amendment to the package leaflet, which were requested by the authorities, were welcomed by Centaur as they lead to an expansion of the pool of patients. All further questions from the representatives of the authority could be answered fully and satisfactorily.

In the official protocol of the meeting, made available in October, the contents of the meeting and the positive results are confirmed. The commission gives a clear recommendation to grant permission for the market admission of DermaPro®, and to issue the necessary import approvals. Thus the prerequisites have been fulfilled to receive the approval document very soon and to launch the „New Chemical Entity“ DermaPro® in the large and important Indian market.

The application for registration was already submitted to the Indian authorities at the end of 2013 after Centaur had completed a phase III trial with 310 patients in which the excellent efficacy of DermaPro® was confirmed: Already after 10 weeks, the wound surfaces had at least halved for 92% of the patients, i.e. a continuing healing process had been initiated. For 76% of the patients, a complete closure of the chronic wounds could be achieved after 10 weeks. After the market launch, this new medication will finally be available for the millions of patients in India.

PRESS RELEASE



CytoTools

Our Partner, the Centaur Pharmaceuticals company, has already drawn up a detailed marketing concept which, among other measures, also includes scientific symposia in which the medical profession are to be informed about the innovations and the breakthrough in the treatment of chronic wounds.

As already reported, the treatment of patients has been completed in the corresponding European study on diabetic foot. Delays in data transfer from some Hungarian centres means that the data cleansing can be expected by mid November. The final results will be available by the end of November at the latest.

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:

CytoTools AG is a German biotechnology company focused on translating fundamental biology research on the mechanisms of cell growth and programmed cell death into unique therapies that are designed to treat the cause of the disease rather than the symptoms. The Company has developed a robust and diverse pipeline of disease modifying therapies that comprise proprietary small molecules and biologics. These have the potential to provide new treatment options in dermatology, cardiology and angiology, urology and oncology. CytoTools AG is structured as an investment and holding company and as such holds investments in its subsidiaries DermaTools Biotech GmbH (55%) and CytoPharma GmbH (42%).

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