PRESS INFORMATION

Successful dialogue with the American Food and Drug Administration (FDA) regarding the expansion of the DermaPro® clinical trials programme for the indication ulcus cruris in the USA

- At a Pre-IND meeting with the American regulatory authority FDA, the conditions for a clinical trial in the indication ulcus cruris (leg ulcer) in the USA were discussed.

- After examining the available preclinical and clinical data, the FDA confirmed that CytoTools can now submit the application to carry out a clinical trial with DermaPro in the USA within the scope of an IND (Investigational New Drug) also with regard to a later marketing approval in the USA.

- At a second meeting with the FDA, after the IND has been granted, the results of the European ulcus cruris phase II/III trial are to be presented. Should the results of this trial correspond with the expectations, then subsequently a phase III trial in the USA can be carried out directly as a confirming, registration-relevant trial.

Darmstadt, 13th May 2015 – The DermaTools Biotech GmbH, a subsidiary of the CytoTools AG, presented DermaPro® to the American authorities for the first time at a so-called Pre-Ind meeting with the FDA on 29th April 2015. The aim was to prepare the clinical trial authorisation for DermaPro® in the ulcus cruris („open leg sore“ or Venous Leg Ulcer (VLU) indication. After a fundamentally positive evaluation, the authorities proposed that an application should be made for a formal IND, whereby in dialogue, all relevant results are to be evaluated and judged in detail. When the IND status has been granted, and the expected positive data of the European phase II/III trial is available, the design of the confirmatory phase III ulcus cruris trial should be then discussed at a further meeting with the FDA. This trial is relevant for new drug approval both in the USA and in Europe for the ulcus cruris indication.

Ulcus cruris is one of the most common conditions affecting older patients worldwide. In the USA alone, up to three million patients (more than 1 % of the population) suffer from this disease and their therapy is both protracted and expensive. It is estimated that the therapy costs of venous leg ulcers consume between 1 and 3 % of the total health budget of the USA. Depending on the size and duration of the wound up to 80 % of the ulcers are considered incurable.

„For DermaTools, the Pre-IND meeting with the FDA in Washington was a first, very important step towards the US approval of DermaPro®. For the first time we were able to present our active substance in detail to this important registration authority, and we did it very successfully. “, Dr. Weißbach, Chief Medical Officer of CytoTools, explained. „From now on, we want to work very closely with the FDA in order to obtain IND status for DermaPro quickly.“

Dr. Weißbach continued: „What must be seen as a very positive development here is that the authorities have indicated that, in case of positive results from the European trial, they are prepared to permit a confirmatory phase III trial directly, without a further phase I or phase II trial. The proviso here is that the results of the European trial are as positive as we have already seen in the indication diabetic foot and in the phase II trial in Europe.“ Favourable results in the phase III trial would then mean that registration applications could be submitted parallel in Europe and the USA for the VLU indication.

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 (57%) and CytoPharma GmbH (42%).

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