PRESS RELEASE

CytoTools AG: European trials on diabetic foot and ulcus cruris (leg ulcers) on schedule - Delay in the market approval for the wound healing agent DermaPro® in India

- Over 95 % of the necessary patients recruited for trials in the indications diabetic foot ulcers (DFU) and ulcus cruris in Europe
- Market approval of DermaPro® in India delayed due to the queries relating to dermatological, toxicological animal study
- The three-month test was already started in February by our licensee partner Centaur as a precautionary measure

Darmstadt, 4th March 2015

European Phase III Programme continues according to schedule

DermaTools Biotech GmbH, a subsidiary of CytoTools AG, announced that the clinical trial programme for the European market in the indications diabetic foot (DFU) and ulcus cruris (VLU) is proceeding according to plan. In the meantime, more than 295 patients have already been recruited in the ongoing DFU trial and more than 75 patients have been recruited for the VLU trial. Therefore, we have already been successful in recruiting more than 95% of the required patient number in both trials. „In the 2nd quarter of 2015, we are expecting the intermediate results of the double-blind VLU trial for the very important European market“, commented Dr. Weissbach, the CytoTools executive responsible for regulatory approval. He added: „The observations made to date make us optimistic that the trial can be moved forward to phase III without delay. The safety profile of the active substance DermaPro® has been excellent in all previous trials. With the completion of the recruiting for the phase III diabetic foot trial according to plan, and allowing for an average treatment period of three months, we expect to obtain the trial results in summer 2015. This will be an important step on the road to European registration“

Indian registration authorities have asked for a toxicological animal study

In meetings beginning of December 2014 in Delhi it was confirmed that all the required documentation had been submitted and that market approval for India could be granted in the short term. DermaTools and their partner Centaur have already successfully treated over 400 patients with DermaPro® during a period up to four month. Nevertheless, data were requested from a sub-chronic, dermal, toxicological investigation in animals over a three month period.

And this, although positive European toxicological tolerance trials are available and the fact that human results are always classed higher than animal investigations. The executive management of DermaTools and licensee partner Centaur did not want to carry out this trial – also from an animal ethics perspective.

Now, however, as a precautionary measure, Centaur has started corresponding animal trials in February 2015 because to date there has been no written confirmation from the authorities regarding the necessity of such a trial.

Short term registration nevertheless possible

In spite of this, short term registration is still possible because fundamentally all the necessary documents have been submitted to the authorities. In the pharmaceutical industry the usual period for obtaining registration for an innovative new drug is between 18 and 30 months. Therefore, DermaTools and Centaur are still within the usual time frame as documents were first submitted 14 months ago.

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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