



CytoTools announces positive intermediate results for the European ulcus cruris trial – seamless transition into an approval-relevant phase III trial with less number of patients

- Positive results in the intermediate evaluation of the ulcus cruris trial
- Continuation of the trial as an approval-relevant phase III trial with a total of 260 patients
- Proof of efficacy for further important indication in the wound healing field

Darmstadt, 29th June 2015 – The DermaTools Biotech GmbH, a subsidiary of the CytoTools AG, has received the recommendation from the independent „Data and Safety Monitoring Board“ (DSMB), appointed to evaluate the trial, to continue with the current DermaPro[®] trial for the ulcus cruris indication. This recommendation was given after the evaluation of the data from the first 80 patients showed an extremely successful healing process.

The protocol of this double-blind trial, which commenced in September 2014, stipulates an intermediate evaluation after 80 treated patients. The active substance DermaPro[®] is being tested in comparison with the current standard treatment, a moist wound dressing. With this standard treatment, at present, only about 30 % of the patients achieve a complete wound closure. The intermediate analysis, which has now taken place, should also provide information on how many more patients must be treated in order to demonstrate a statistically significant treatment success in all three primary target parameters. These are composed of the reduction in the absolute wound size, the percentage of patients with a wound reduction of more than 50 % and a complete wound closure. The intermediate analysis came to the conclusion that a total of 260 patients should be treated in the trial. DermaTools must therefore recruit a further 180 patients for the trial so that the expected results are statistically relevant and reliable.

Dr. Weissbach, the Chief Medical Officer of CytoTools AG, explained here: „The fact that the independent DSMB now recommends that DermaTools continue the trial as phase III, with a relatively small number of patients, means that it is extremely probable that the trial goals can indeed be reached. We consider this to be a great success.“ He continued: „Although at the moment we do not yet know the exact results, apparently, for ulcus cruris as well, DermaPro is demonstrating a clear superiority in comparison with the standard treatment. The decision of the DSMB confirms our interpretation of the currently still blinded data. If the trial results are so positive, this would mean that in future DermaPro can be used to treat chronic wounds of all different kinds, and thus, for the first time in decades, there would be the first really new drug available for treating such patients.“

PRESSE RELEASE



CytoTools

Ulcus cruris (colloquially “ulcerated leg”) is the most frequently diagnosed chronic wound in the older population and represents 70 % of all non-healing wounds.

The treatment of ulcus cruris is protracted and expensive: In German speaking counties alone, it is estimated that the health insurance companies must spend 2 billion euros per annum for the treatment costs.

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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