



**CytoTools AG reports: The active substance DermaPro® retains its potential**

- **Concentration of the active substance in the phase III study on diabetic leg wounds far below the specifications given by CytoTools**

**Darmstadt, 9<sup>th</sup> December 2015** – Over the last one and a half weeks, the CytoTools AG has made an intensive study of all the responsible parameters for the results of the phase III trial on the treatment of diabetic leg in Europe. The complete data was carefully studied after it became available at the beginning of last week. The data evaluation itself, the preparation of the trial medication as well as the batches of trial medication used were examined for possible errors. After no anomalies could be determined in the distribution between countries, or within the centres, the analysis of the batches of trial medication delivered the first concrete results. The first batch which was used showed a trend towards more efficacy in comparison with controls – even if this trend was weaker than previous studies had led us to expect. The second batch used showed, as with the final results, no difference in comparison with the active controls. After these results became known, a chemical analysis of the batches used in the trial was commissioned from several independent, officially certified test institutes. Their analyses showed that the first batch contained a concentration of DermaPro® of only maximum 50 % of the specification ordered by CytoTools and the second batch contained a maximum of merely 10 % of the active substance values required, i.e. much lower still than the first batch.

The reason for this massive non-conformance can not be finally evaluated at the moment.

After this new analysis, the trend towards efficacy in the trial was demonstrated in the batch with the higher concentration in the subgroup analysis in this trial.

For CytoTools AG, the active substance DermaPro® therefore continues to retain the therapeutic potential demonstrated in the previous successful clinical trials.

The CEO, Dr. Mark-Andre Freyberg, added: „ We regret that the publication of the summary results the week before last caused a massive fall in share prices. At the time, we had absolutely no idea how this, for us so unexpected, result could have come about. We shall continue our analyses intensively in order to determine the causes of the low active substance concentrations and then put a stop to this.“

Dr. Freyberg added further, “In spite of the unsatisfactory results of the phase III clinical trial in Europe, in my opinion, the therapeutic potential of the active substance DermaPro® remains. We will continue to analyse the results and deduce options for subsequent steps.

## **PRESS RELEASE**



# CytoTools

„We are relieved that we have found a plausible explanation for these results which were not comparable with the successful results of previous studies.“, said Dr. Markus Weissbach, the member of the board responsible for clinical trials. „We see in the batch which had 50 % of the expected active substance concentration, a trend towards efficacy which provides the beginning of a dose-effect curve. This will help us in planning future trials because we now know the no-effect threshold.“

For CytoTools AG, with the results of the phase III trial, a corporate situation has occurred where the most important factor now is to win back lost confidence and trust. Here, the CytoTools AG has the benefit that the company has no debts and adequate funds to continue with current projects.

*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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