



**CytoTools AG: The CytoTools subsidiary DermaTools Biotech GmbH files action for damages against the active substance manufacturer.**

- *The background circumstances and causes of the too low active substance concentration of the trial samples used in the European trials have been explained*
- *The far too low concentration of DermaPro® is the result of an error in production and in the analysis of the active substance solution by the contract manufacturer*
- *A lawsuit with corresponding claims for damages has been brought before the competent court*

**Darmstadt, 26<sup>th</sup> August 2016** – In a multi centre, European phase III trial for the diabetic foot indication, and a multi centre, European phase II trial for Ulcus cruris, with the wound healing medication DermaPro® from CytoTools' subsidiary DermaTools Biotech GmbH, surprisingly, results were obtained which deviated from previous clinical trial findings. The reason is now known: the cause is a far too low concentration of active substance. Depending on the batch, the actual active substance concentration was at least either 50 % or 90 % below the concentration which was required from the contract manufacturer and also 50 % or 90 % below the figures stated on his analysis certificate. Due to this fact, already with the supply and release of the batches of the trial medication, the associated clinical trials were doomed to failure. In the past months, DermaTools, together with experts, have carried out exhaustive analyses of the manufacturing process and the analytical procedures. Now, with a new manufacturer, faultless manufacturing and analysis is safeguarded in future. The analysis was augmented by a further determination which excludes that the error, which with a correct manufacturing procedure does not occur, remains unrecognised.

Until recently, DermaTools was in contact with the manufacturer in order to find an amicable solution for the great damage which has been caused. Unfortunately, these consultations have not led to a satisfactory result. After obtaining a legal appraisal of the situation by a renowned law firm specialised in pharmaceutical law, a lawsuit with claims for damages from the manufacturer, has been brought before the competent court. Details cannot be given here as the matter is now sub judice.

*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.*

## **PRESSE RELEASE**



# CytoTools

### **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 (58%) and CytoPharma GmbH (42%).

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