



CytoTools AG: For the first time, results from the phase II/III trial on the treatment of Ulcus cruris (venous leg ulcer, “open leg” ulcer) confirm the clinical efficacy of DermaPro® in this indication. Previously, the efficacy of the medication had only been tested in the indication diabetic foot.

- A complete wound closure was achieved in 50 % of the patients suffering from Ulcus cruris treated with DermaPro®. Averaged over all treated patients the wound size decreased by 62 % in relation to the initial value.
- Outstanding tolerance of the active substance is confirmed
- The trial is terminated after the intermediate evaluation.

Darmstadt, 23.05.2016: DermaTools GmbH, a subsidiary of the CytoTools AG, reports on the results of a European phase II trial with DermaPro® in the treatment of chronic Ulcus cruris. This European phase II trial was carried out over a period of one year in three countries as a double-blind, randomised comparative trial. After treating 110 of the planned 260 patients the trial was terminated because the reanalysis of the batch of active substance used, due to a production error, was only 50 % of the concentration prescribed by DermaTools in the specification for the trial.

The results which have been achieved are therefore all the more remarkable:

Only patients who had suffered a particularly long and severe course of the disease were included in this trial. In contrast to most trials in this indication, which limit the duration of the disease (< 1 year) and the size of the wounds (< 5 cm²), here patients were included with an average wound anamnesis of over 2 ½ years and an average wound size of 15 cm². „To date, in these cases which are particularly difficult to treat, a complete wound healing can only be achieved in about 20 % of the cases.“, explained Dr. med. Markus Weissbach, medical director of the CytoTools AG. And: „We were all the more surprised that a complete wound closure was achieved in 50 % of the patients. Thus we recorded a 250 % higher healing rate than is described in the literature concerning these types of patients. These results, accompanied by an average wound size reduction of > 62 %, are clinically relevant and were superior to the reference therapy – physiological saline solution, although statistical significance was not achieved due to the small number of patients. More than 77 % of the patients treated achieved a healing of over 50 % of the wound area and are therefore classified as responders“.

Dr. Weissbach stressed, „these good results were obtained using only half the foreseen active substance concentration which indicates that a treatment with the correct concentration can produce clearly greater healing successes“.

The tolerance of DermaPro® was excellent and showed no differences to the reference therapy or to the previous studies on the diabetic foot indication.

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„These positive results encourage us to actively pursue this indication and to repeat this trial as quickly as possible with the originally intended higher active substance concentration. The preparations here have already begun. We see the great potential of the active substance DermaPro[®], also in this trial on Ulcus cruris!“, commented Dr. Mark-André Freyberg, chairman and CEO of the CytoTools AG.

Ulcus cruris is the most commonly diagnosed chronic wound among the elderly population and represents 70 % of all non-healing wounds. The treatment of Ulcus cruris is protracted and expensive: In German-speaking countries alone, the estimated burden on the public health budget is estimated at more than 2 billion € per annum, also because there is no standard therapy available.

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:

The **CytoTools AG**, previously CytoTools GmbH, is a technology holding and investment company which holds shares in its subsidiary companies in the pharmaceutical and medical products field: about 58 % of DermaTools Biotech GmbH (therapy field - dermatology, urology) and 42% of the CytoPharma GmbH (therapy field cardiovascular disease, cancer). The complete know-how is protected by corresponding basic patents which are maintained worldwide by CytoTools AG and it is transferred by the CytoTools AG to the associated companies in the form of worldwide exclusive licenses.

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