Corporate News

First results of the European clinical dose-finding study show clear superiority of DermaPro® in comparison with the control treatment for diabetic foot wounds

- Treatment with DermaPro® leads to clearly higher complete wound closure in comparison with control treatment
- Optimal concentration for treatment determined
- All DermaPro® concentrations used demonstrated excellent tolerance

Darmstadt, 14th August 2019 – The CytoTools AG (WKN: A0KFRJ; ISIN: DE000A0KFRJ1) reported today on the first results of the European dose-finding study, carried out by its subsidiary DermaTools Biotech GmbH. After treatment had been completed, at the end of June, on the last patient in the phase II trial with DermaPro®, now, the first results of the statistical evaluation are available. All the concentrations of DermaPro® which were used showed clear superiority in the most important parameter – complete closure of the wounds. This applies both to the concentration which was used previously in the successful trials in India, as well as the twofold and fourfold higher concentrations also used here. The comparison here was not against placebo, but against the best moist wound dressing, proposed by the treating physicians, (Hydrogel) of the latest generation (standard therapy). With this, a point of criticism on the previous moist dressing control treatment was dispelled. Then, also in comparison with the most modern wound bandage, DermaPro® showed its clear superiority.

The results showed that the 1.2 mM concentration of the active substance DermaPro® used previously, provided almost double the number of wound closures in comparison with the controls, and is therefore clearly superior. In a comparison of the different DermaPro® concentrations, the concentration used hitherto was also confirmed as the most suitable. It could not be demonstrated that an increase in the concentration of the active substance provided further advantages. Thus the previously used concentration is obviously already providing an active substance optimum and a further increase has no added effect. It was confirmed, therefore, that the concentration used to date is the best treatment option.

Furthermore, these results confirmed the excellent safety profile of DermaPro®. This remained the case even at the higher concentrations, where a fourfold increased dosage was applied without any undesired side effects.

The process of data evaluation is now being continued in detail and definitively analyzed. Concurrently, the work continues on submitting the application for the coming European phase III clinical trial with DermaPro® in the diabetic foot indication. The applications for approval of this phase III trial will be expanded by the results of this study, and the application will be made for the original concentration of the active substance.

As reported earlier, the choice of additional suitable centers for the phase III trial has already commenced, and the contacts to the existing centers will be intensified, so that after the final trial approval, the recruiting of patients can make a speedy start.

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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 (62%) and CytoPharma GmbH (50%).