Corporate News

The complete evaluation of the results of the European clinical dose-finding study confirms: Treatment with DermaPro® demonstrates clear superiority in comparison with controls, in the treatment of diabetic foot wounds.

- Wound treatment with DermaPro® leads to complete wound closure in very significantly more cases than with control treatment.
- The active substance dosage used previously in treatment has been confirmed
- Excellent tolerance evidenced
- Application documents for the subsequent phase III trial near completion

Darmstadt, 4th December 2019 – The CytoTools AG (WKN: A0KFRJ; ISIN: DE000A0KFRJ1) reports today that its subsidiary, DermaTools Biotech GmbH, now have the final evaluation of the dose-finding study available. According to this evaluation, the first preliminary results, already reported at the beginning of August, now, as a result of the detailed evaluation, have been confirmed in full. Due to a new orientation of the commissioned clinical research organization after a takeover, the final results were presented with a two month delay.

In comparison with controls, all the implemented concentrations of DermaPro® demonstrated clear superiority for the parameter – the complete closure of the wounds - which is now considered to be the most important target by the registration authorities. In the trial, the control treatment (standard therapy) was carried out with the method which the treating physicians consider to be currently the best treatment which would normally be applied in such cases – a moist wound dressing (Hydrogel) of the latest generation. Also in comparison with this most modern wound dressing, DermaPro® demonstrated its clear superiority. Thus a point of criticism of the previous control treatments- – that a simple moist dressing of gauze and physiological saline does not comply with the clinical standard - could also be dispelled.

Summarizing, the formulation used previously, and in India the now registered composition, with a concentration of the active substance DermaPro® of 1.2 mM, demonstrated, with almost twice the number of wound closures, its clear superiority in the treatment of diabetic foot ulcer, highlighting the corresponding clinical significance and relevance.

Fortunately, this observation is enhanced by a significant improvement in the symptoms such as pain and pruritis which normally accompany the diabetic foot indication. According to the results of the trial, an increase in the active substance concentration does not bring any further advantages and, as expected, a reduction in active substance concentration weakens the healing effect. Thus the concentration used to date lies within the active substance optimum and is therefore confirmed as the best treatment option.

Through this confirmation of the concentration, and in particular in combination with the begin of sales in India with the same active substance concentration, synergistic effects will be obtained. As treatment begins in India, a large volume of patient data will be obtained providing comprehensive safety information and documented therapy results, which could also be used for an indication extension.

Overall, the results confirm that the excellent safety profile of DermaPro® remains intact – even if higher concentrations are applied - and that in spite of a multiplication of the dosage, no side effects were recorded.

As we reported, the preparations for the application for carrying out the European phase III trial are nearing completion. To finalize the application, a request regarding the trial protocol and trial design was submitted to the European Medicines Agency. We expect to receive the meeting protocol shortly.

Furthermore, the selection of additional suitable counties and centers for the phase III trial has already begun, and the contacts with the existing centers are being further intensified. Therefore, after receipt of the final trial approval, patient recruiting can begin promptly and quickly.

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This information 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%).