PRESSEINFORMATION

The CytoTools AG explains the causes of the insufficient active substance concentration which led to the unexpected results of the European phase III trial in the diabetic foot indication.

- *The manufacturers did not adhere to the specifications they were given due to a combined error of a handling mistake in production and in the analysis.*
- *Strict compliance with the manufacturing instructions and an additional control analysis within the scope of the release analytics will exclude these errors in future.*
- *For Europeans needs, negotiations will be held with qualified contract manufacturers.*
  We shall also examine the possibility of establishing a further – second – manufacturing of the worldwide patented active substance under our own control.
- *The trial will be repeated in the short term and subsequently we shall submit for EU approval.*

Darmstadt, 26th January 2016 – As we reported earlier, the wound healing medication DermaPro® from CytoTool's subsidiary DermaTools Biotech GmbH did not produce the expected results in the European phase III trial for the diabetic foot indication. The reason for this has been identified as a completely insufficient active substance concentration. Depending on the batch, the actual content of DPOCl was at least 50 to 90 % below the concentration assigned for the trial. Because the control group was treated with the current recommended standard (dressing moistened with physiological common salt solution) as the comparison, none of the trial patients had disadvantages due to the insufficient concentration.

How such an active substance dosing error occurred was clarified by a comprehensive analysis of the medication, the treatment and the drug manufacturing. The decisive error can be described as follows:

The re-examination showed that a foreign substance was included in the active substance batches in question during production. This substance is for the treated patients completely harmless. In the analytics, it is detected with the same chemical analysis as the active substance molecule itself and – if present – simulates an increased concentration of DermaPro.

This problem complex of the possible formation of this foreign substance was known to the manufacturer, and because the processes in manufacturing and analyses were carried out correctly it did not occur in earlier batches.

Within the scope of the release analytics, DermaTools will include an additional determination method which responds when this foreign substance occurs due to a manufacturing error.

This ensures that this problem is taken into account during the concentration determination of DPOCl.

Thus, in future, we know reliably that the final concentration of active substance is accurate and that errors in the manufacturing procedures are eliminated.

The DermaTools Biotech GmbH has contacted the manufacturer with a view to examining possible consequences. In addition, we are taking legal advice from a renowned firm of lawyers specialising in pharmaceutical law. In this connection, we are examining the possibilities of damage claims against the manufacturer.

In summary, it can be concluded that the cause of the unsatisfactory results of the diabetic foot trial has been found. The error which occurred can be excluded in future if procedures in manufacturing and analysis are followed correctly. Because the results of the trial show that even a low concentration of the medication produces a clear effect, the trial for the diabetic foot indication can be repeated at short notice with a smaller group of patients. Talks with qualified manufacturers in Europe have begun. Furthermore, we are examining the possibility of a further – second – production of the worldwide patented active substance under our own supervision.

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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