PRESSE RELEASE

An extended strategy should considerably accelerate the development of the CytoTools AG.

- Data from the European phase III study can be used in part
- As well as the known strategy for registration of a new drug, a second marketing possibility in the field of medical products will be pursued.

Darmstadt, 31st January 2017 Dr. Wilfried Hauke, the new Chief Medical Officer of the CytoTools AG, presented a revised strategy for the marketing of the active substance DermaPro®. According to this, the registration of DermaPro® as a new drug will continue to be pursued with a modification of the previous development strategy, which fundamentally targets repeating clinical phase III. The new aspect of the strategy is that now an additional development of this active substance in a lower dosed variation is planned, with the aim of obtaining market approval as a medical product throughout Europe. The great advantage is that medical products can be developed much faster and at a lower cost, because there are different requirements in comparison with obtaining new drug approval.

This additional, and in the medium term, considerable potential for the product development was identified within the scope of a renewed evaluation of the data of the phase III trial in Europe, which, due to a lower active substance concentration had not achieved the intended results. The evaluation showed however, for these important indications of chronic wounds, (for which worldwide no effective therapy is available), that the active substance DermaPro® remains a major source of hope. Then, in this completed phase III trial in Europe, at an active substance concentration of less than 50 % of the originally intended dosage, efficacy could still be detected.

In this way, progress could be made with two promising product developments in the field of chronic wounds. Chronic and poorly healing wounds in the lower extremities, as often occur as a result of diabetes, are a growing, and very serious medical problem worldwide. Examinations by the „International Diabetes Federation“ estimates that the total number of diabetes sufferers worldwide in 2014 now exceeds 390 million people. In Germany alone, there are more than 5 million diabetes patients. Due to circulatory disorders, damage to nerves and a lowered pain threshold, up to 20 % of all diabetes patients develop a diabetic leg condition which in many cases requires amputation. Worldwide, there is no approved drug which offers an effective solution for this group of patients.

For registration as a medical product the Medical Products Law is applicable. This states which criteria must be fulfilled in order to obtain a CE marking. For this, appointed authorities (e.g. the TÜV, the German Technical Inspection Association) are engaged which carry out the process together with the developing company. The CytoTools AG has obtained a first expertise which comes to the conclusion that this procedure is feasible and recommends obtaining the agreement of a national health authority. In case of a positive decision, the molecule dichloric acid with a lower concentration (e.g. 50 %) could be granted a CE marking as a medical product and then, within a very short time, be marketed throughout Europe.

A further advantage is that new clinical trials would not be necessary because the dossiers, which have to be compiled, could make reference to the data on the supporting effectiveness and excellent tolerance of the completed phase III trial. This will also be possible according to the new Medical Device Regulation MDR 2017. This procedure would be much faster and clearly cheaper to implement as the application for new drug approval running parallel. The corresponding steps with the aim of obtaining certification as a medical product are currently being prepared.

Dr. Mark-Andre Freyberg, the CytoTools CEO, explained here: „The new development strategy has the great advantage that the patented molecule dichloric acid can be brought to market much faster and at a much lower cost. All preclinical data on the new active substance have already been obtained for the new drug development, and the idea of using the clinical data from the European phase III trial with a reduced active substance concentration, could, retrospectively, prove to be a windfall. Further clinical studies would thus not be necessary. This will still be the case when the new medical products regulation comes into force, probably in 2017. Due to the excellent tolerance and the available clinical data on dichloric acid, the search for a marketing partner in the medical products field could begin this year, because, after approval by a national health authority, a launch of our molecule as a medical product under the CE marking would be possible in Europe. The further development as a drug in a higher concentration could then occur concurrently and would complete the overall development and the value-adding chain."

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 biological and chemical active substances effective against the causes of disease. 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 (57%) and CytoPharma GmbH (42%).

Contact:

CytoTools AG
Dr. Mark Andre Freyberg
Klappacher Str. 126
D-64285 Darmstadt
Tel.: +49-6151-95158-12
Fax: +49-6151-95158-13