



CytoTools AG: Subsidiary DermaTools Biotech starts European clinical phase II/III trial with wound healing medication DermaPro® for ulcus cruris indication

- Clinical application dossier for a phase II/III trial regarding indication ulcus cruris (venous leg ulcers) submitted to European authorities
- Study with about 160 patients at renowned European centres
- Ulcus cruris – most common cause of chronic leg wounds with medically unsatisfactory treatment success

Darmstadt, 5th May 2014 – the DermaTools Biotech GmbH, a subsidiary of the CytoTools AG, has initiated the first European, multicentric, double-blind, phase II/III trial of its wound healing medication DermaPro® for the ulcus cruris indication. For this purpose, the corresponding application documents have been submitted to the responsible health authorities. The trial should provide proof that DermaPro® can not only be used very successfully in the previous indication of „diabetic foot syndrome“, but also in the much more common disease „ulcus cruris“ (venous leg ulcers) - strongly accelerating and completing the healing of these chronic wounds.

After the very promising results in the previous clinical trials with diabetic foot ulcer, now the therapeutic spectrum is to be extended to include the indication venous leg ulcers which is much more common than the diabetes complication. If, after the intermediate evaluation, the very good results of the diabetic foot trials are confirmed, this trial is planned to be extended so that it can become a phase III trial. With the corresponding results, this could lead to a direct approval application for an indication extension.

Chronic and poorly healing wounds on the lower leg are caused to over 70 % by ulcus cruris venosum and/or ulcus cruris postthromboticum. The majority of those affected are older and female. A characteristic feature of these wounds is a very poor healing tendency – the average healing duration amounts to more than 24 weeks. Moreover, many of these ulcers are completely resistant to therapy. The open wounds have a very negative influence on the quality of life – pain, itching and an offensive smell – and lead to very intensive care requirements and finally to high treatment costs. In Germany alone, the statutory health insurance funds spend more than EUR 1 billion annually on the treatment of these conditions.

Thus, for a population which is steadily growing older, leg ulcers are becoming an increasing socio-economic problem. „Hundreds of thousands of people are affected in Germany alone by this socially isolating disease which is severely detrimental to the quality of life. A large meta-analysis, which was carried out a few years ago, showed that there is still no satisfactory local medicinal treatment.“ Dr Markus Weissbach, Chief Medical Officer at CytoTools, explained. There is no conservative therapy with prospects of success apart from elaborate elastic dressings or compression stockings which need changing every day.

PRESSE RELEASE



CytoTools

„A successful therapy of this serious, tedious and insufficiently treatable disease would mean a medical breakthrough which millions of patients are waiting for worldwide.“ Dr. Weissbach added. Within the scope of the Europe-wide indication-specific study, independently from the results of the intermediate analysis, about 160 patients at 15 renowned European dermatological or angiological centres are to be treated - thus completing an important step towards the indication extension for DermaPro®. „After completion of the trial with positive results, the application will be submitted for authorisation of an indication expansion“, Dr. Weissbach said.

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.

CytoTools AG, previously CytoTools GmbH, is a technology and holding company which holds the following shares in its subsidiaries which carry out product development in the pharmaceutical and medical products field: around 57% in DermaTools Biotech GmbH (therapy field dermatology, urology) and 46% in 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 transferred to the subsidiary companies in the form of exclusive licenses.

Contact:

CytoTools AG
Dr. Mark Andre Freyberg
Klappacher Str. 126
D-64285 Darmstadt
Tel.: +49-6151-95158-12
Fax: +49-6151-95158-13
E-Mail: freyberg@cytotools.de

Press contact:

cometis AG
Ulrich Wiehle
Unter den Eichen 7
D-65195 Wiesbaden
Tel.: +49-611-205855-11
Fax: +49-611-205855-66
E-Mail: wiehle@cometis.de