



CytoTools AG: Clinical development program for the wound healing drug DermaPro® now extended to US pharmaceuticals market

- Clinical Phase 3 study in preparation for US approval of DermaPro® in the ulcus cruris (venous leg ulcer=VLU) indication
- Close liaison with FDA to agree study design should facilitate VLU study launch in first half of 2015
- Clinical development work progressing on schedule for diabetic foot ulcer (DFU) and ulcus cruris (VLU) indications in Europe

Darmstadt, November 17, 2014

Clinical development program for DermaPro® in the US

DermaTools Biotech GmbH, a subsidiary of CytoTools AG, plans to submit an investigational new drug (IND) application to the FDA for DermaPro® in november. After a pre-IND meeting in the 1st quarter of 2015 and once clinical investigation approval has been obtained, the multicenter Phase 3 study in the ulcus cruris indication is to be performed in specialist centers in the US. The start date of this study is planned for the first half of 2015.

The ulcus cruris (venous leg ulcer/VLU) condition, colloquially referred to as a “leg ulcer”, is also very widespread in the US. Between 1.5 million and 2 million new US patients each year are affected and treatment is both protracted and expensive. The costs of treating VLU are estimated to account for between 1% and 3% of the overall US healthcare budget. Despite manifold attempts at treatment, many ulcers cannot be healed within two years.

“Performing a clinical study in this major indication in the US is a further important step in the planned global marketing of DermaPro®”, comments Dr. Weissbach, Chief Medical Officer at CytoTools. “In close cooperation and liaison with the FDA, the US approval authority, we aim to access the world’s most important pharmaceuticals market. At the planned meeting with the FDA in early 2015 (pre-IND meeting), based on the European data already available we will agree with the FDA which additional data has to be generated in the US in the planned Phase 3 study. The aim is to be able to apply for US approval with the data then combined from Europe and the US.”

European Phase 3 study progressing on schedule

The European clinical trial program in the diabetic foot ulcer (DFU) and ulcus cruris (VLU) indications continues to progress on schedule. Within the expected timeframe, more than 260 patients have already been included in the current DFU study and more than 60 patients in the VLU study.

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“Even though the double-blinded nature of the VLU study means we cannot yet report on the effectiveness of the drug, the observations by our investigating physicians make us very optimistic”, added Dr. Weissbach. “To date, they have not observed any side-effects, thus indicating a superb compatibility profile. It is especially important for long-term therapies that no local or generalized allergic reactions should arise.”

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 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 (57%) and CytoPharma GmbH (42%).

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