

PRESS RELEASE

Adocia announces topline results of Indian Phase 3 trial of BioChaperone PDGF for diabetic foot ulcer

- BC PDGF did not meet the primary endpoint in this Phase 3 trial conducted in India
- BC PDGF was confirmed to be safe and well tolerated

Lyon, August 25 2016 - Adocia (Euronext Paris: FR0011184241 – ADOC), a clinical stage biopharmaceutical company focused on the treatment of diabetes with innovative formulations of approved proteins, today announced topline results from a Phase 3 clinical trial of BioChaperone PDGF (BC PDGF) in the treatment of diabetic foot ulcer (DFU), which was conducted in India.

In this trial, BC PDGF did not meet the primary endpoint of a statistically significant improvement over placebo in complete wound closure after twenty weeks of treatment. There were no safety concerns attributed to BC PDGF.

"We are surprised and disappointed by these topline results, which are inconsistent with previously reported positive Phase 1/2 clinical results. Therefore, we have initiated a thorough review of the study to analyse the discrepancy in the data" said Gérard Soula, CEO of Adocia. "However, diabetic foot ulcer has proved an extremely difficult condition to address, as seen in multiple recent late-stage clinical trial failures. The main reason is the lack of uniformity in the standard of care of these types of wounds. In this context, we have decided to halt all development work in this indication. As announced previously, we are focusing our efforts on our portfolio of innovative injectable therapeutics for the treatment of diabetes."

This randomized, double-blind, multicenter, outpatient study enrolled 252 diabetic patients from India with a chronic DFU. In addition to standard of care, each group of patients was treated every two days for a maximum of 20 weeks with either a placebo spray (saline solution) or a spray containing BC PDGF.

Adocia would like to thank all participating patients and trial investigators for their commitment.



About Diabetic Foot Ulcer

Diabetic foot ulcer is a severe complication of diabetes. DFUs are chronic wounds, for which secondary infection can lead to amputation. Treatment options remain limited and in many countries the only approved biological product to treat this disease is Regranex® (Smith & Nephew, gel of PDGF for topical application).

In a previous Phase 1/2 clinical trial, Adocia's BioChaperone PDGF spray formulation showed a wound closure efficacy at least equivalent to Regranex's efficacy, at one-third the weekly dosage and when applied half as often.

About ADOCIA

Adocia is a clinical-stage biotechnology company that specializes in the development of innovative formulations of already-approved therapeutic proteins. Adocia's insulin formulation portfolio, featuring four clinical-stage products and one preclinical product, is among the largest and most differentiated in the industry.

The proprietary BioChaperone® technological platform is designed to enhance the effectiveness and/or safety of therapeutic proteins while making them easier for patients to use. Adocia customizes BioChaperone to each protein for a given application in order to address specific patient needs.

Adocia's clinical pipeline includes four novel insulin formulations for the treatment of diabetes: two ultra-rapid formulations of insulin analogs (BioChaperone Lispro U100 and U200), a rapid-acting formulation of human insulin (HinsBet U100) and a combination of insulin glargine and a rapid-acting insulin analog (BioChaperone Combo). Adocia is also developing an aqueous formulation of human glucagon (BioChaperone Glucagon) and a concentrated, rapid-acting formulation of human insulin (HinsBet U500), both at a preclinical stage of development.

In December 2014, Adocia signed a partnership with Eli Lilly for the development and commercialization of the BioChaperone Lispro projects.

Adocia aims to deliver "Innovative medicine for everyone, everywhere."

To learn more about Adocia, please visit us at www.adocia.com







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