Press release

ADOCIA reports positive phase II clinical results for the treatment of diabetic foot ulcer

- **ADOCIA's spray formulation of PDGF-BB (Platelet Derived Growth factor), combined with BioChaperone®, has been evaluated versus Regranex®, gel of PDGF-BB recognized as the gold standard for diabetic foot ulcer treatment**
- **This clinical trial meets the main objectives with a dose reduction by three of the growth factor contained in Regranex® and a reduction of the frequency of application, once every two day versus every day for Regranex®**
- **This efficient, easy-to-use and cost-effective product could represent an important opportunity for the 10 million patients worldwide who are suffering from diabetic foot ulcers**
- **ADOCIA is planning a phase III clinical trial, in India, in the fourth quarter of 2012, in order to register its product in emerging countries in late 2014. In the same time ADOCIA is actively preparing phase III clinical trials in the United States and Europe for the second half of 2013**

Lyon, 23 April 2012 – ADOCIA (NYSE Euronext Paris: FR0011184241 - ADOC), a biotechnology company specialized in the development of best-in-class medicines with already approved therapeutic proteins, announces today positive results from its Phase II clinical trial evaluating the safety and efficacy of BioChaperone® combined with PDGF-BB for the treatment of diabetic foot ulcer. This product has been compared with Regranex®, a commercially available hydrogel of PDGF-BB (HealthPoint, initially launched by Johnson & Johnson).

The multicentric trial has enrolled 192 patients in 4 groups consisting in the application of one of the three doses of BioChaperone PDGF-BB (14.5, 43.75 and 87.5 µg of PDGF-BB per cm² and per week) and Regranex® (43.5 µg per cm² and per week). BioChaperone PDGF-BB treatments were administered once every two days whereas Regranex® was administered once a day, in compliance with the trial protocol that was approved by both US and European regulatory agencies. The trial was not blinded due to the obvious difference in the medications, a spray for BioChaperone PDGF-BB and a gel for Regranex®. Treatments lasted 20 weeks or until complete healing.

The objective of the study was to establish the non-inferiority of BioChaperone PDGF-BB compared to Regranex®.

Analysis of negative side effects, collected through the intent-to-treat (ITT) population of 192 patients did not identify any serious side effect related to the treatment. These safety results indicate that BioChaperone PDGF-BB is well tolerated and safe at the three doses tested, for treatment periods up to 20 weeks.

The primary endpoint is the percentage of complete wound closure at 20 weeks. The rates of complete wound closure are all superior or equal to 66% after 20 weeks, therefore proving success on non-inferiority criteria for the three tested PDGF-BB doses.

One of the most promising results is the 80% rate of complete wound closure at 20 weeks obtained with the dose of BioChaperone containing one-third of the Regranex® equivalent of PDGF-BB dose and with only one application every two days.

For the three tested doses, secondary efficacy endpoints, ie the percentage of complete wound closure at 10 weeks, the time to achieve complete wound closure (expressed by Kaplan-Meier median) and the percentage of reduction in wound area are all considered as non-inferior compared to Regranex®.

Dr. Arun Bal (Mumbai), principal investigator of the study said: "*We were very pleased to conduct this clinical study on this attracting product which showed undisputed efficacy. The simplicity of*

use of the spray as well as the frequency of application once every two days had a very positive impact on patient compliance and was very well received among patients".

"The results obtained with one-third of the dose of PDGF-BB with the BioChaperone PDGF-BB spray pave the way for a cost-effective treatment in this disease affecting 10 million people worldwide. Cost of treatment is a key issue not only in emerging countries but also in the western countries." declared Dr Gérard Soula, Chairman & CEO of ADOCIA.

These clinical results will be presented in major scientific congresses on wound healing, at the European Wound Management Association in Vienna, Austria, on May 23-25, 2012 and at the World Union of Wound Healing Societies in Yokohama, Japan on September 2-6, 2012.

"We are now actively preparing a phase III trial which could be launched in the fourth quarter of 2012 in India and two phase III clinical trials in the United States and in Europe planned for the second half of 2013. The Indian study should be the last step before marketing the product in emerging countries", noted Dr Olivier Soula, VP R&D director of ADOCIA.

About BioChaperone PDGF-BB

BioChaperone PDGF-BB is a topical aqueous sterile formulation administered via a multidose spray device. Comparison of theoretical treatment dosing and dose effectively delivered from the container in the 4 treatment groups suggested a very good compliance to study medication for BioChaperone PDGF-BB doses, whereas large discrepancies between theoretical and used amounts of Regranex® gel were observed.

BioChaperone PDGF-BB is a formulation comprising PDGF-BB and one polymer of the proprietary BioChaperone® platform. Adocia specifically designed this polymer to form a molecular complex with PDGF-BB to protect it from enzymatic degradation. This protection sustains the efficacy of PDGF-BB and permits to reduce the frequency of application by two and even to reduce the dose by three.

BioChaperone also stabilizes PDGF-BB in the vial at neutral pH for 3 months at room temperature. The spray device guarantees the sterility of the solution after multiple uses. This property permits to avoid the usage of antibacterial agents which are deleterious for cell proliferation.

About Diabetic Foot Ulcer

15% of diabetic patients will develop a diabetic foot ulcer in their lifetime. Diabetic foot ulcer is a major and increasing public-health problem. Foot ulcers cause substantial morbidity and are a leading cause of amputations. The number of amputations per year, worldwide, due to diabetes is estimated at over one million. Moreover, diabetic foot ulcer multiplies by 2.4 the risk of death of the patient.

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About ADOCIA

"Innovative medicine for everyone, everywhere"
ADOCIA is a biotechnology company specialized in the development of best-in-class medicines with already approved therapeutic proteins.
ADOCIA is specialized in insulin therapy and the treatment of the diabetic foot ulcer, one of the main complications of diabetes. Worldwide, more than 366 million individuals are currently suffering from diabetes (with a forecast of 552 million individuals by 2030, i.e. a 51% increase, reaching 70% in emerging countries). 15% of these patients will develop a foot ulcer during their lifetime. The markets targeted by ADOCIA represent more than USD 20 billion (USD 17 billion for insulin therapy and USD 3 billion for diabetic foot ulcer

healing).
Through its BioChaperone® state-of-the-art technological platform, Adocia enhances the effectiveness and safety of therapeutic proteins and their ease of use for patients, with the aim of making these medicines accessible to the broadest public.
ADOCIA successfully completed two phases I and II studies on the formulation of a fast-acting human insulin and obtained promising phase I/II results on a diabetic foot ulcer healing product. Adocia also confirmed the value of its technology for the formulation of a fast-acting insulin analog by signing an exclusive worldwide license agreement with a major pharmaceutical company. Furthermore, Adocia is developing a unique combination of fast-acting insulin and slow-acting insulin, for an optimal insulin therapy with one single product.

To be a global leader for the formulation of therapeutic proteins

Based on its experience and recognised know-how, ADOCIA has extended its activities to the formulation of monoclonal antibodies, which are gold standard molecules for the treatment of numerous chronic pathologies (oncology, inflammation, etc.). In this field, ADOCIA is engaged in collaborative programs with two major pharmaceutical companies.
ADOCIA's therapeutic innovations aim at bringing solutions to a profoundly changing global pharmaceutical and economic context, characterised in particular by the increased prevalence and impact of the targeted pathologies, population growth and ageing, the need to control public health expenditures and increasing demand from emerging countries.
ADOCIA is listed on the regulated market of NYSE Euronext in Paris (ISIN Code: FR0011184241, mnemonic code / Reuters / Bloomberg: ADOC, ADOC.PA, ADOC.FP), and its share is included in the Next Biotech index.
For more information: www.adocia.com

Disclaimer

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