Adocia Launches Phase III Clinical Study in India Of Treatment for Diabetic Foot Ulcer

Study aims to support marketing approval of BioChaperone PDGF-BB in India and other emerging countries

Lyon, France, August 25th, 2014 - Adocia (Euronext Paris: FR0011184241 – ADOC) announced today the initiation of a clinical Phase III study in India of BioChaperone® PDGF-BB, the Company’s innovative formulation of Platelet Derived Growth Factor (PDGF-BB) for the treatment of diabetic foot ulcers. This follows the approval given by the Drug Controller General of India (DCGI) on August 22nd, 2014. The dossier for this clinical trial was filed in September 2012, but the processing of the application had been delayed by the internal reorganization of the Indian regulatory agency.

This Phase III clinical trial is designed to confirm on a large population the efficacy of BioChaperone PDGF-BB spray to treat diabetic foot ulcer. Its results are expected to be used to support registration and market approval in India and in several other emerging countries. This double-blind, multicenter study will enroll 252 diabetic patients with a chronic foot ulcer. The main efficacy endpoint is complete wound closure after a maximum 20 weeks of treatment. Secondary efficacy criteria include wound closure at 10 weeks and the rate of reoccurrence three months after closure. Results of this study are expected in the first quarter 2016.

Olivier Soula, General Deputy Manager and Director of R&D at Adocia stated, “We are very pleased to have obtained the Indian Agency’s approval to begin this clinical study, which, should it be successful, would support marketing approval of Adocia’s product in India as well as in several other emerging countries. In keeping with the European Medicine Agency’s validation of our clinical pathway, the results of this study would be supportive to our European dossier, and only one Phase III clinical study in Europe would be required. Accordingly, we also continue preparing our clinical dossier for a European Phase III study.”

Diabetic foot ulcer is a severe complication of diabetes. These ulcers 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-BB for topical application). In a previous Phase II clinical trial, Adocia’s BioChaperone PDGF-BB 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. The wounds healed with BioChaperone PDGF-BB also showed a lower risk of reoccurrence, which should limit the risk of amputation. The reduced frequency of application with BioChaperone PDGF-BB should also reduce
the cost of care, by minimizing hospital and other costs (dressings, etc.). The three-time reduction of the weekly dose of product should also lower the total cost of treatment.

“Diabetic foot ulcer affects millions of patients throughout the world. We are convinced that BioChaperone PDGF-BB could be a breakthrough for these patients by offering a more effective and affordable treatment,” stated Gérard Soula, CEO of Adocia. “In line with our dual strategy for gaining approval in western and emerging countries, we made the strategic decision to develop this innovative treatment first in India, where the diabetic population has reached 65 million and where the PDGF-BB therapeutic protein is already approved.”

About diabetes
Diabetes is a chronic condition in which the person has high blood glucose (hyperglycemia), either because insulin production is inadequate, or because the body's cells do not respond properly to insulin, or both. Chronic hyperglycemia contributes to disease progression and results in macrovascular and microvascular complications. Diabetes, which today affects, more than 382 million individuals worldwide, is forecasted to grow to 592 million individuals by 2035, an average increase of 55%, and an increase of as much as 70% in emerging countries. (Source: International Diabetes Federation, 2013).

About diabetic foot ulcer
Diabetic foot ulcer (DFU) is one of the main complications of diabetes, with about 15% of diabetic patients estimated to develop DFU during their lifetime (Ramsey & al, Diabetes Care 1999, 22 (3), 382-387). Consequences may be severe, including limb amputation, and mortality rates at 5 years are comparable to those of colon cancer (Armstrong et al, Int. Wound J. 2007, 4(4), 286-87). The cost of care for these patients in the United States is estimated to be twice as high as for diabetic patients without foot ulcers. (Rice et al, Analysis Group, I. Medical, Drug, and Work-Loss Costs of Diabetic Foot Ulcers. ISPOR 18th Annual International Meeting, 2013). In 2010, the advanced wound care market was worth $3.4 billion (BCC Research).

About BioChaperone PDGF-BB
BioChaperone PDGF-BB (BC PDGF-BB) is an innovative formulation of Platelet-Derived Growth Factor, one of the main growth factors naturally responsible for normal wound healing. In a chronic wound, PDGF-BB gets degraded; the use of Adocia’s proprietary BioChaperone technology protects and stabilizes PDGF-BB, extending its positive action on wound healing. During a first Phase II clinical study performed in India on 192 patients with diabetic foot ulcer, BC PDGF-BB showed it was at least as efficient as Regranex at one third of the weekly dosage and when applied half as often. Moreover, BC PDGF-BB is formulated as a spray of an aqueous sterile solution, stable at room temperature, which limits any risk of product degradation due to mishandling.

In 2013, Adocia solicited the European Medica Agency’s (EMA) Scientific Advice to validate BC PDGF-BB clinical development plan in Europe. This advice confirmed that the results of the present Phase III clinical study in India could be considered supportive to the registration dossier in Europe. Consequently, only one European Phase III clinical study should be needed to complete the European registration dossier (instead of the usual two).

About Adocia
To be a global leader in the innovative delivery of insulins and therapeutic proteins
Adocia is clinical-stage biotechnology company that specializes in the development of innovative formulations of already-approved therapeutic proteins. It has a particularly strong expertise in the field of insulins. Adocia's proprietary BioChaperone® technological platform is designed to enhance the effectiveness and safety of therapeutic proteins and their ease of use for patients.

Adocia has successfully completed two Phase I and IIa studies of a fast-acting human insulin formulation (HinsBet), two Phase I and IIa studies of an ultra-fast-acting insulin lispro (BioChaperone Lispro U100) and a Phase I/II of a unique combination of insulin glargine, the gold-standard of basal insulin and insulin lispro, a
fast-acting insulin analog (BioChaperone Combo) and one Phase II clinical study of its product based on PDGF-BB for treating diabetic foot ulcer (BC PDGF-BB).

A dose-escalation Phase IIa study of BioChaperone Lispro U100 is ongoing. The German regulatory agency approved in July 2014 the start of a Phase IIa clinical study for HinsBet and a dose-escalation Phase IIa study of BioChaperone Combo is scheduled for the fourth quarter 2014. The company is also preparing a first clinical study of a new ultra-fast concentrated insulin formulation based on insulin lispro (BioChaperone Lispro U300) for 2015.

Adocia has extended its activities to the formulation of monoclonal antibodies, which are gold-standard biologics for the treatment of various chronic pathologies (cancer, inflammation, etc.). Adocia is engaged in collaborative programs with two major pharmaceutical companies in this field.

**Fighting cancer with targeted treatments**

DriveIn® is a nanotechnology which is remarkably efficient in delivering active compounds into cancer cells. This new platform constitutes an exceptional opportunity to enter the oncology market by improving the efficacy of both already approved treatments and novel proprietary molecules.

**“Innovative medicine for everyone, everywhere”**

Adocia’s therapeutic innovations aim at providing solutions in a profoundly changing global pharmaceutical and economic context, characterized by (i) an increased prevalence and impact of the targeted pathologies, (ii) a growing and ageing population, (iii) a need to control public health expenditures and (iv) an increasing demand from emerging countries.

Adocia is listed on the regulated market of Euronext Paris (ISIN: FR0011184241; Reuters/Bloomberg ticker: ADOC, ADOC.PA, ADOC.FP) and is included in the Next Biotech index. American Depositary Receipts representing Adocia common stock are traded on the US OTC market under the ticker symbol ADOCY. For more information, visit [www.adocia.com](http://www.adocia.com)

**Safe Harbor**

This press release contains certain forward-looking statements concerning Adocia and its business. Such forward-looking statements are based on assumptions that Adocia considers to be reasonable. However, there can be no assurance that the estimates contained in such forward-looking statements will be verified, which estimates are subject to numerous risks including the risks set forth in the ‘Risk Factors’ section of the Reference Document registered by the Autorite des marches financiers on April 24, 2014 under number R.14-020 (a copy of which is available on www.adocia.com) and to the development of economic conditions, financial markets and the markets in which Adocia operates. The forward-looking statements contained in this press release are also subject to risks not yet known to Adocia or not currently considered material by Adocia. The occurrence of all or part of such risks could cause actual results, financial conditions, performance or achievements of Adocia to be materially different from such forward-looking statements. This press release and the information contained herein do not constitute an offer to sell or the solicitation of an offer to buy Adocia shares in any jurisdiction.

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