PRESS RELEASE

Adocia announces its phase III development program for the treatment of diabetic foot ulcer

This program has been validated by scientific advice from the European Medicines Agency

Lyon, France, March 18, 2013 - Adocia (NYSE Euronext Paris: FR0011184241 - ADOC), a biotechnology company specialized in the development of ‘best-in-class’ medicines from already approved therapeutic proteins announces today the phase III development program of its product, BioChaperone® PDGF-BB for the treatment of diabetic foot ulcer (DFU). The European Medicines Agency (EMA) issued positive scientific advice for this program.

Adocia has developed a unique formulation, a BioChaperone PDGF spray for the treatment of DFU. Based on the positive results of the phase II clinical trial in India, Adocia has filed a dossier for a phase III clinical trial there. This dossier is currently under review by the DCGI (Drugs Controller General of India). The trial should permit Adocia to file a request for marketing authorization in India and other emerging countries.

Meanwhile, Adocia is actively preparing a clinical program for marketing the product in Europe and the United States of America.

In Europe, Adocia is focusing on the treatment of neuroischemic DFU which is the most frequent form of the disease with 60% of the patients. It is the most difficult to heal with a high rate of amputation. There is currently no approved treatment for neuroischemic DFU. Therefore, there is a medical need for this indication which should facilitate the regulatory approval of a treatment for the disease. In order to validate the regulatory pathway for the Marketing Authorization Application (MAA), Adocia has asked for scientific advice from the EMA.

The EMA agrees that only one phase III study conducted in Europe would be required for the MAA. In addition, the clinical data from the phase III trial in India would be admissible to the MAA.

The EMA advice also included agreement on the design and protocol features of the Phase III trial. The pivotal phase III clinical trial in Europe is designed to assess the efficacy of BioChaperone PDGF-BB compared to a placebo for the treatment of neuroischemic DFU. The trial is expected to be launched in mid 2014.
“This Scientific Advice from the EMA which validates our clinical program in Europe is an important milestone. We are now preparing the submission of the clinical development plan for the FDA in the USA” said Olivier Soula, Director of R&D and Deputy General Manager, Adocia.

“This positive advice was critical in order to move forward in our discussions with potential partners as it helps to define budget and milestones until commercialization” said Gérard Soula, President & CEO of Adocia.

Next scheduled events

- March 21, 2013 – Presentation meeting to investors, SFAF, at Euronext (Paris)

Adocia will attend Future Leaders in Biotech in New York (USA) on April 5, 2013.

About Adocia:

"Innovative medicine for everyone, everywhere"
Adocia is a biotech company specialized in the development of best-in-class drugs from the innovative formulation of certain already-approved therapeutic proteins.
Adocia is specialized in insulin therapy and the treatment of the diabetic foot, 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 intends to enhance 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 recognized 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 in a profoundly changing global pharmaceutical and economic context, characterized 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: FR0011184241, mnemo / Reuters / Bloomberg: ADOC, ADOC.PA, ADOC.FP) and its share included in the Next Biotech index Next Biotech.
For more information: www.adocia.com

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