

# PRESS RELEASE

# Adocia announces the initiation of a clinical trial on its combination of the long-acting insulin Glargine and a fast-acting insulin analog

This phase I/II clinical trial on Type 1 Diabetics seeks to compare the performance of this Combo based on insulin Glargine with HumalogMix®

**Lyon, November 13, 2013 -** Adocia (NYSE Euronext Paris: FR0011184241 - ADOC), a biotechnology company specializing in the development of 'best-in-class' medicines from already approved therapeutic proteins, announces today that it has launched the first clinical trial of its innovative formulation combining insulin Glargine (Lantus<sup>®</sup>, Sanofi), the gold-standard of long acting insulin, to a fast-acting insulin analog, insulin Lispro (Humalog<sup>®</sup>, Eli Lilly). This unique combination is made possible thanks to the BioChaperone<sup>®</sup> technology developed by Adocia, which makes insulin Glargine compatible with fast-acting insulin analogs.

This clinical trial aims to demonstrate that the combination could offer diabetic patients improved glycemic control compared to a Premix of insulin analog such as HumalogMix, based on insulin Lispro (Eli Lilly), or NovoMix®, based on insulin Aspart (Novo Nordisk). Hence, pharmacodynamic and pharmacokinetic profiles of the combination BioChaperone Glargine/Lispro will be compared to the pharmacodynamic and pharmacokinetic profiles of HumalogMix in a cross-over design on 20 Type 1 diabetic patients under euglycemic clamp. The first patients of this double-blind study conducted in Germany have already been dosed

Today, Type 1 and Type 2 diabetic patients requiring intensive insulin therapy have two treatment options: either a Premix, which is a formulation of a single insulin with both fast and long actions, or an association of two products, a long-acting insulin and a fast-acting insulin. The current gold-standard of long-acting insulin is Lantus, which generated \$6.5 billion in 2012.

Premix products, NovoMix (Novo Nordisk) and HumalogMix (Eli Lilly), ease everyday life for diabetics, who can manage their glycaemia using only one product injected twice daily. These Premix have been commercialized for more than ten years and generate annual revenues of more than \$2.3 billion, with significant growth in emerging markets. However,

these products put patients at higher risk of hypoglycemia compared to separate injections of Lantus and a fast-acting analog insulin.

"There is a real need to provide patients using Lantus and a fast-acting insulin with the simplicity afforded by Premix products, as well as to offer Premix-using patients the greater medical efficacy obtained with Lantus, real gold-standard," said Gérard Soula, Adocia's CEO. This combination could therefore extend Glargine's market potential towards the Premix market. This Combo based on insulin Glargine, insulin off-patent in 2015, has been internationally patented in 2012."

"Adocia's BioChaperone proprietary technology allows for a clear and stable solution of insulin Glargine and a fast-acting analog insulin, two products that are not compatible under natural conditions," explains Olivier Soula, Deputy General Director and R&D Director at Adocia. "In this clinical trial, we are testing one of the potential combinations but alternative combinations, namely with insulin Glulisine (Apidra®, Sanofi) and insulin Aspart (NovoLog®, Novo Nordisk) have also been validated in preclinics."

Results from this study are expected during the first quarter of 2014.

### **Next event**

Adocia will attend **ODDO Midcap Forum**, Lyon, France – January 9<sup>th</sup> and 10<sup>th</sup>, 2014.

#### **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 USD20 billion (USD17 billion for insulin therapy and USD3 billion for diabetic foot ulcer healing).

Through its BioChaperone<sup>®</sup> 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. 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 to 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.

For more information: www.adocia.com

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#### Disclaimer

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 Autorité des marchés financiers on April 25, 2013 under number R13-017 (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.