



PRESS RELEASE

Adocia initiates BioChaperone® Lispro comparative study to validate THDB insulin lispro for Phase 3 BC Lispro trials in Europe and U.S.

- The purpose of the comparative study is to demonstrate safety and efficacy of BioChaperone® Lispro (BC Lispro) using Tonghua Dongbao (THDB) lispro as the drug substance.
- In nine previous studies, BC Lispro demonstrated significant improvement compared to Humalog®, Aspart® and Fiasp®, while also proving to be safe and well tolerated.
- Trial design approved by BfArM and FDA to enable pivotal Phase 3 trials in Europe and U.S.

Lyon, France, July 30th, 2020 – 6:00pm CEST- Adocia (Euronext Paris: FR0011184241 – ADOC- the “Company”), a clinical stage biopharmaceutical company focused on the treatment of diabetes and other metabolic diseases with innovative formulations of approved proteins, announced today the initiation of a comparative study to demonstrate safety and efficacy of BC Lispro using with insulin lispro manufactured by Tonghua Dongbao in patients with type 1 diabetes. The authorization from the German Federal Institute for Drugs and Medical Devices *Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM)* was granted on July 21st, 2020. In addition, the U.S. Food and Drug Administration (FDA) granted approval for the Investigational New Drug (IND) application on July 29th, 2020. The approvals by BfArM and the FDA ensure a clear path to initiate pivotal Phase 3 trials for BC Lispro in Europe and the U.S. following a successful comparative study.

“We are pleased to obtain the approval from the German BfArM and the U.S. FDA to initiate this comparative study required before Phase 3,” commented Olivier Soula, Deputy CEO of Adocia. *“We thank Tonghua Dongbao team for this impressive work which is an important step to deliver this product to patients worldwide.”*

The CT037 study compares BC Lispro manufactured with insulin lispro from Tonghua Dongbao to US-approved Humalog® and EU-approved Humalog® reference products so the results allow to address US and EU markets. Additionally, the study also includes the comparison with BioChaperone reconstituted with Humalog® (Eli Lilly), as used by Adocia in previous Type 1 diabetes trials.

The four arms of the CT037 trial:

- BioChaperone® with insulin lispro from Tonghua Dongbao
- BioChaperone® reconstituted with Humalog®
- US-Humalog® alone
- EU-Humalog® alone

The randomized, double-blind, crossover trial will be performed in Germany with 28 type 1 diabetes patients, coordinated by Profil, a German full-service CRO specialized in diabetes and obesity.

About BioChaperone® Lispro

BioChaperone® Lispro (BC Lispro) is an ultra-rapid formulation of prandial insulin lispro that incorporates Adocia's BioChaperone® proprietary technology. BioChaperone® is designed to enable the acceleration of insulin absorption. BC Lispro has previously demonstrated an accelerated insulin action profile across nine Phase 1/2 studies in people with type 1 and type 2 diabetes compared to insulin analog lispro (Humalog®, Eli Lilly) and insulin aspart (Novolog®, Novo Nordisk), administered either with insulin syringes or by insulin pumps. Moreover, BC Lispro U100 has demonstrated significant improvement in terms of performance compared to Humalog® across six clinical studies.

Since 2018, Adocia and Chinese company Tonghua Dongbao have a strategic alliance to develop and commercialize BC Lispro in China and other Asian and Middle East territories. In addition, Tonghua Dongbao supplies Adocia with insulin lispro and insulin glargine globally (with the exception of China), enabling Adocia to advance its key programs BioChaperone Lispro and BioChaperone Combo and to diversify partnership opportunities. Adocia retains the rights to develop BC Lispro in the US, Europe, Japan and Latin America and the formulation is already set for licensing in these regions.

For more information on BC Lispro, please visit our website: www.adocia.com/products/biochaperone-ultra-fast-analog-insulin

About Adocia

Adocia is a clinical-stage biotechnology company that specializes in the development of innovative formulations of therapeutic proteins and peptides for the treatment of diabetes and metabolic diseases. In the diabetes field, Adocia's portfolio of injectable treatments is among the largest and most differentiated of the industry, featuring five clinical-stage products and three preclinical-stage products. 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.

Adocia's clinical pipeline includes four novel insulin formulations for prandial treatment of diabetes: two ultra-rapid formulations of insulin analog lispro (BioChaperone® Lispro U100 and U200), a combination of basal insulin glargine and rapid-acting insulin lispro (BioChaperone® Combo) and one combination of a prandial insulin with amylin analog pramlintide M1Pram (ADO09). The clinical pipeline also includes an aqueous formulation of human glucagon (BioChaperone® Glucagon) for the treatment of hypoglycemia.

Adocia preclinical pipeline includes three products: a combination of rapid human insulin analogues and Pramlintide (BioChaperone® LisPram), a combination of insulin glargine with GLP-1 receptor agonists (BioChaperone® Glargine GLP-1) for the treatment of diabetes and a ready-to-use combination of glucagon and a

GLP-1 receptor agonist (BioChaperone® Glucagon GLP1) for the treatment of obesity.

In 2018, Adocia and Chinese insulin leader Tonghua Dongbao entered a strategic alliance. In April 2018, Adocia granted Tonghua Dongbao licenses to develop and commercialize BioChaperone Lispro and BioChaperone Combo in China and other Asian and Middle Eastern territories. The licensing agreements included USD 50 million upfront and up to USD 85 million development milestones, plus double-digit royalties on sales. In June 2018, Tonghua Dongbao agreed to manufacture and supply active pharmaceutical ingredients insulin lispro and insulin glargine to Adocia globally, excluding China, to support Adocia's portfolio development and commercialization.

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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