Adocia and Lilly report positive Phase 1b topline results on the post-meal effect of ultra-rapid BioChaperone Lispro in patients with type 1 diabetes

Lyon and Indianapolis, June 26, 2015 – Adocia (Euronext Paris : ADOC) and Eli Lilly and Company (NYSE: LLY) announced today the completion of a Phase 1b clinical trial evaluating BioChaperone Lispro, an ultra-rapid formulation of insulin lispro licensed to Lilly. This formulation uses Adocia’s proprietary technology BioChaperone, which is designed to accelerate insulin absorption.

This completed study, part of the Adocia-Lilly partnership, aimed to compare the effects of BioChaperone Lispro and Humalog® (insulin lispro rDNA origin) when injected at mealtime on post-prandial glycemic control in type 1 diabetes patients. While commercialized fast-acting insulin analogs are injected five to 15 minutes before or immediately after a meal, an ultra-rapid insulin may allow injection at the time of the meal, or even after the start of a meal while improving post-prandial glycemic control.

“We are very pleased to announce these first positive clinical results from a Phase 1b study in collaboration with Lilly,” states Olivier Soula, Adocia’s R&D Director and Deputy General Manager. “This successful trial is solid ground for further establishing the medical benefit of our ultra-rapid insulin formulation for people with diabetes.”

In this crossover, randomized, double-blind meal study, 38 people with type 1 diabetes received a 0.2 U/kg dose of either BioChaperone Lispro or Humalog just prior to a standardized meal. The primary endpoint was a comparison of the post-meal glycemic excursions over the first two hours (Delta-AUC-BG(0-2h)). BioChaperone Lispro was associated with a 61 percent reduction in post-prandial glucose excursion over the first two
hours compared to Humalog (Delta-AUC-BG(0-2h) ratio = 0.39; 95%-CI 0.28 to 0.52; p<0.0001).

The study also provides confirmation of the ultra-rapid pharmacokinetic profile of BioChaperone Lispro. These results are consistent with previous clinical findings from NCT02146651 demonstrating BioChaperone Lispro has a significantly faster rate of insulin lispro absorption than Humalog with an increase in the early insulin exposure of 168 percent at the same dose (AUClispro_0-30min ratio = 2.68; 95%-CI 2.18 to 3.30; p<0.0001).

In terms of safety, BioChaperone Lispro and Humalog led to similar numbers of hypoglycemia episodes. No local reactions were seen on the site of administration for either treatment.

"We remain committed to providing novel solutions to patients with diabetes including those who require insulin therapy" said David E. Moller, Vice President, Endocrine and CV Research and Clinical Investigation, Lilly Research Laboratories. "The data we have generated together with Adocia is encouraging and we look forward to learning more about how this potential new treatment option may work in people with diabetes.”

Additional clinical studies will be conducted this year in order to prepare the Phase 3 clinical plan.

The registry on clinicaltrials.gov for this trial (2014-005028-92) has been updated.

This press release contains forward-looking statements about the research collaboration between Adocia and Lilly related to BioChaperone Lispro and reflects Lilly's current beliefs. However, there are substantial risks and uncertainties in the process of drug research, development, and commercialization. There is no guarantee that the research collaboration will yield successful results or that either company will achieve the anticipated benefits, or that BioChaperone Lispro will achieve additional positive study results, or will achieve regulatory approval. For further discussion of these and other risks and uncertainties, see Lilly's filings with the United States Securities and Exchange Commission. Lilly undertakes no duty to update forward-looking statements.

About Eli Lilly and Company

Lilly is a global healthcare leader that unites caring with discovery to make life better for people around the world. We were founded more than a century ago by a man committed to creating high-quality medicines that meet real needs, and today we remain true to that mission in all our work. Across the globe, Lilly employees work to discover and bring life-changing medicines to those who need them, improve the understanding and management of disease, and give back to communities through philanthropy and volunteerism. To learn more about Lilly, please visit us at www.lilly.com and http://newsroom.lilly.com/social-channels.

1 Adocia’s press release on September 09, 2014 « Adocia Reports Positive Preliminary Results from Dose Response Clinical Study of Ultra-fast acting BioChaperone® Lispro U100 in Patients with Type 1 Diabetes”
About Adocia

Adocia is a 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. To learn more about Adocia, please visit us at www.adocia.com.

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