Adocia and Lilly announce positive topline results from a Phase 1b study of repeated administration of ultra-rapid BioChaperone Lispro U100 in people with type 2 diabetes

- BioChaperone® Lispro demonstrated an ultra-rapid pharmacokinetic profile with a statistically significant 83 percent increase in exposure to insulin lispro over the first 30 minutes after injection compared to Humalog
- BioChaperone Lispro and Humalog® showed similar safety results in subjects with type 2 diabetes and were well tolerated

Lyon and Indianapolis, April 27, 2016 – Adocia (Euronext Paris: ADOC) and Eli Lilly and Company (NYSE: LLY) announced today positive topline results from a Phase 1b clinical trial under the Adocia-Lilly partnership evaluating BioChaperone Lispro, an ultra-rapid formulation of insulin lispro licensed to Lilly. This formulation uses Adocia’s proprietary technology BioChaperone, designed to accelerate insulin absorption.

This study was the first to evaluate BioChaperone Lispro in people with type 2 diabetes, who unlike people with type 1 diabetes, may show various degrees of disease progression, endogenous insulin production, and insulin resistance. The 14-day, outpatient study aimed to compare the effect of multiple daily injections of BioChaperone Lispro and Humalog (insulin lispro rDNA origin) on post-prandial glycemic control relative to solid standardized meals, when injected at the time of the meal, in 51 people with type 2 diabetes.

“We are delighted to also observe in people with type 2 diabetes a significantly faster insulin absorption with BioChaperone Lispro compared to Humalog, as was the case in our previous studies in people with type 1 diabetes. This acceleration translated, across more than 200 meal tests, into a significant reduction in post prandial glucose excursion over the first two hours. These results underscore that BioChaperone Lispro delivers a similar performance in people with type 1 or type 2 diabetes,” said Simon Bruce, MD, Adocia’s Chief Medical Officer. “This study also reinforces comparability in the BioChaperone Lispro safety profile to that of Humalog.”
In this double-blind, randomized, crossover study, 51 subjects with type 2 diabetes used individualized doses of either BioChaperone Lispro or Humalog as the short acting insulin in their multiple daily injection regimen, injected at the time of the meal over two periods of 14 days. At the beginning (Days 1 and 2) and the end (Days 13 and 14) of each period, subjects were subject to a meal tolerance test in the clinic to compare post-prandial blood glucose profiles after identical bolus injections of either BioChaperone Lispro or Humalog immediately before a solid standard meal. Based on a post-hoc analysis that include all four meal tolerance test for each treatment, BioChaperone Lispro demonstrated a statistically significant 22 percent reduction in blood glucose excursion over the first two hours compared to Humalog. The pharmacokinetic profile of BioChaperone Lispro U100 was consistent with that observed in previous studies in people with type 1 diabetes, demonstrating a statistically significant 83 percent increase in exposure to insulin lispro over the first 30 minutes compared to Humalog.

“We are encouraged by the results of this trial,” said Thomas Hardy, M.D., Senior Medical Director, Endocrinology, Eli Lilly and Company. “In addition, we are pleased with the expeditious progress of our joint program with Adocia.”

Both BioChaperone Lispro and Humalog were similarly well tolerated throughout each 14-day period. No obvious differences in adverse events or injection site reactions and no differences in the overall incidence of hypoglycemia were seen. No new or unexpected safety findings were observed.

The registry on clinicaltrials.gov for this trial (NCT02562326) has been updated.

This press release contains forward-looking statements about the research collaboration between Adocia and Lilly related to BioChaperone Lispro and reflects Adocia’s and 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 risks and uncertainties and more generally of the risks related to the businesses of Lilly and Adocia, see Lilly’s filings in the United States with the United States Securities and Exchange Commission (SEC) and Adocia’s filings in France with the French Financial Markets Authority (Autorité des marchés financiers – AMF). Neither Lilly nor Adocia undertake any duty to update such 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.
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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