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

- At the beginning of each 14-day treatment period, BioChaperone Lispro U100 demonstrated a statistically significant 31 percent reduction in blood glucose excursion over the first two hours compared to Humalog injected at the time of a solid meal.

- After 14 days of treatment, a statistically significant 42 percent reduction in blood glucose excursion over the first two hours was observed with BioChaperone Lispro U100 over Humalog, when the treatments were injected at mealtime.

- BioChaperone Lispro and Humalog showed similar safety results in the outpatient setting and were well tolerated.

Lyon and Indianapolis, March 14, 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 outpatient 14-day study comparing 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 in 36 patients with type 1 diabetes. The study also investigated the effects of different timing of administration, with treatments being injected either at mealtime, 15 minutes before, or 15 minutes after the start of a solid meal. Whereas commercialized fast-acting insulin analogs are usually injected before the meal, an ultra-rapid insulin aims to allow injection at the time of the meal, or even after the start of a meal, while maintaining a reduction in the magnitude of glycemic excursions.
“We are extremely pleased to confirm that BioChaperone Lispro consistently delivered superior post-prandial control compared to Humalog, especially after a real-life solid meal. BioChaperone Lispro proved to offer a robust performance throughout the study period,” said Simon Bruce, MD, PhD, Adocia’s Chief Medical Officer. “We also saw excellent preliminary safety results in the outpatient setting, with no observed difference between the treatments.”

In this double-blind, randomized, crossover study, 36 patients with type 1 diabetes used individualized doses of either BioChaperone Lispro or Humalog as the short acting insulin in their multiple daily injection regimen, over two periods of 14 days. At the beginning and the end of each period, patients were subject to a meal tolerance test in the clinic to compare post-prandial blood glucose profiles after identical bolus injections immediately before the meal of either BioChaperone Lispro or Humalog relative to a solid standard meal. At the beginning of the study, when injected at the time of meal, BioChaperone Lispro demonstrated a statistically significant 31 percent reduction in blood glucose excursion over the first two hours compared to Humalog. After 14 days of treatment for each treatment, BioChaperone Lispro also demonstrated a statistically significant 42 percent reduction in blood glucose excursion over the first two hours compared to Humalog, when injected at the time of the meal. This last result demonstrates the robustness of the performance of BioChaperone Lispro on a two week period.

“This was an important study and provides our first experience with repeat doses of this ultra-rapid insulin formulation in an outpatient setting,” said Thomas Hardy, M.D. Ph.D., Senior Medical Director, Lilly Research Laboratories. “We are encouraged by these results and look forward to seeing the results of additional, ongoing studies.”

Both BioChaperone Lispro and Humalog were similarly well tolerated throughout the 14 days. No new or unexpected safety findings were observed and no local reactions were seen on the site of administration for either treatment.

The registry on clinicaltrials.gov for this trial (NCT02528396) 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.

**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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