Adocia and Lilly announce positive topline results from a Phase 1 study evaluating ultra-rapid insulin BioChaperone Lispro U100 in healthy Japanese subjects

Lyon and Indianapolis, May 31, 2016 – Adocia (Euronext Paris: ADOC) and Eli Lilly and Company (NYSE: LLY) announced today positive topline results from a Phase 1 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 enable the acceleration of insulin absorption.

The study, under the Adocia-Lilly partnership, aimed to compare the pharmacokinetic and pharmacodynamic profiles of BioChaperone Lispro to that of Humalog® (insulin lispro rDNA origin) in 15 healthy Japanese subjects placed under euglycemic clamp.

“We are very satisfied with the results of this study in Japanese subjects, which support the faster absorption and more rapid insulin action of BioChaperone Lispro compared to Humalog as well as the linearity of the dose response – all of which we had observed in Caucasian people with type 1 diabetes” says Simon Bruce, Adocia’s Chief Medical Officer. “These results support the inclusion of Japanese subjects with diabetes in the phase 3 program, in line with our global registration plan for the product.”

In this double-blind, randomized, three-period crossover study, 15 healthy Japanese subjects placed under euglycemic clamp received three single dose administrations separated by 1 to 14 days. Each participant was randomly allocated to receive either three single doses of BioChaperone Lispro U100 (0.1, 0.2 and 0.4 U/kg) or one single dose of Humalog U100 (0.2 U/kg) and two single doses of BioChaperone Lispro U100 (0.1 and 0.2 or 0.2 and 0.4 U/kg) on three separate dosing visits. While the study was not powered for statistical analysis, results show an acceleration of BioChaperone Lispro pharmacokinetic and pharmacodynamic profiles relative to Humalog, as well as the linearity of exposure as a function of the dose administered in the pharmacokinetic profile.

Both BioChaperone Lispro and Humalog were similarly well tolerated. No new or unexpected safety findings were observed.

The registry on clinicaltrials.gov for this trial (NCT02660502) 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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