Adocia and Lilly report positive results of a pilot bioequivalence study comparing BioChaperone Lispro U200 to BioChaperone Lispro U100

- BioChaperone Lispro U200, a BioChaperone Lispro formulation at twice the standard insulin concentration, met all pre-specified endpoints, delivering an ultra-rapid profile equivalent to BioChaperone Lispro U100 in an initial pilot study.

- Adocia receives a $10 million milestone payment from Lilly after successful completion of this clinical pilot study.

Lyon and Indianapolis, December 11, 2015 – Adocia (Euronext Paris: ADOC) and Eli Lilly and Company (NYSE: LLY) announced today the successful completion of a preliminary Phase 1 clinical trial evaluating BioChaperone Lispro U200, a concentrated formulation of BioChaperone Lispro, the ultra-rapid formulation of insulin lispro licensed to Lilly. This completed pilot study aimed to determine the potential for bioequivalence of BioChaperone Lispro U200 to BioChaperone Lispro U100 in healthy volunteers.

There is a current trend toward insulin products with a higher concentration, primarily to meet the need for reduced injection volumes. Recently, Lilly’s Humalog® 200 units per mL (U-200), the first concentrated mealtime insulin analog and a new formulation of insulin lispro, was approved and launched in Europe and in the United States. Humalog U200 was established bioequivalent to Humalog 100 units per mL (U-100) in healthy volunteers. However, an ultra-rapid version of concentrated insulin may better mimic the physiological timing of prandial insulin action.

“The excellent results of this pilot study are an important milestone in the advancement of the ultra-rapid BioChaperone Lispro development program,” says Olivier Soula, Adocia’s R&D Director and Deputy General Manager. “The ability of BioChaperone technology to accelerate the absorption of insulin lispro at both U100 and U200 concentrations could play an important role in expanding and strengthening the Humalog franchise.”

In this four-period crossover, randomized, double-blind study, 26 male and female healthy volunteers under euglycemic clamp received two alternate 0.2 U/kg doses of both BioChaperone Lispro U100 and BioChaperone Lispro U200. The primary objective was a comparison of BioChaperone Lispro U200 to BioChaperone Lispro U100 with respect to two
standard bioequivalence parameters, $C_{\text{max}}$ and $\text{AUC}_{\text{lispro}(0-\infty)}$, and two supporting ultra-rapid properties, $\text{AUC}_{\text{lispro}(0-1h)}$ and early $t_{50\%\text{C}_{\text{max}}\text{lispro}}$. Based on pre-defined criteria, the results show that BioChaperone Lispro U200 retained the ultra-rapid profile of BioChaperone U100.

These positive feasibility results support the development of BioChaperone Lispro U200 based on demonstration of bioequivalence.

“It’s important for us to research and understand ways to address the differing needs of people with diabetes,” said Thomas Hardy, M.D., Ph.D., senior director, Lilly Research Laboratories. “With these results, we are encouraged that BioChaperone Lispro may help meet these diverse needs by providing an ultra-rapid prandial insulin that could also be available as a concentrated U200 formulation.”

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 and other risks and uncertainties and more generally of the risks related to the businesses of Lilly and Adocia, see Lilly’s filings 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 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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