



Company Announcement no. 11/2010

To: NASDAQ OMX Copenhagen A/S

Hørsholm, Denmark, July 5, 2010

LifeCycle Pharma Announces Positive Results of Phase 2 Clinical Trial For LCP-Tacro™ in De Novo Kidney Transplant Patients

LifeCycle Pharma A/S (OMX:LCP) today announced positive top-line results from a Phase 2 clinical trial involving 63 patients comparing LCP-Tacro™ tablets administered once daily versus Prograf® (tacrolimus) capsules (Astellas Pharma) administered twice daily in *de novo* kidney transplant patients. These data confirm the previous positive experience with LCP-Tacro™ in stable kidney and liver transplant patients and support comparability of LCP's extended release tablet formulation of tacrolimus when compared to twice daily Prograf® capsules. Further, the results indicate that LCP-Tacro™ tablets may be safely and efficaciously administered once daily immediately following a kidney transplant.

“We are very pleased with the results of the maintenance Phase 2 clinical trial comparing LCP-Tacro™ tablets administered once daily versus Prograf® capsules administered twice daily in *de novo* kidney transplant patients. These results are consistent with previous findings related to LCP-Tacro™,” said Dr. William J. Polvino, President and CEO of LCP. He continued, “There is an enormous unmet need to help improve transplant therapies, beginning with improving the delivery of the gold standard anti-rejection therapy tacrolimus. This potential new therapy continues to build on our commitment to the management of solid organ rejection.”

Results from the 14 day pharmacokinetic (PK) portion of this Phase 2 study have previously been reported in April 2009. After the initial 14 day PK period, patients were maintained on either LCP-Tacro™ or Prograf® for an additional 50 weeks to assess longer-term safety and efficacy in a comparative setting. While not sized and powered to demonstrate safety and efficacy at a statistically relevant level, once daily LCP-Tacro™ appears to be as well tolerated as the currently approved, immediate release, twice daily product Prograf®.

The Phase 3 development program for LCP-Tacro™ consists of an ongoing, fully-enrolled study in 326 patients with stable kidney transplants along with a planned Phase 3 study in *de novo* kidney transplant patients. The latter study is planned to enroll approximately 540 patients, and enrollment is expected to begin later this quarter. The study protocol is currently in active review with the US FDA through the Special Protocol Assessment (SPA) process.

Summary of LCP-Tacro™ (*de novo* Kidney) Phase 2 Clinical Trial Design

The above Phase 2 clinical trial, which commenced enrollment in October 2008, was an open-label, multi-center, prospective, parallel group study in *de novo* kidney transplant patients. The objectives of the study were to determine the pharmacokinetic profile (AUC_{0-24} , C_{max} , C_{min} , and



T_{max}), safety and efficacy of LCP-Tacro™ tablets once daily versus Prograf® capsules twice daily. *De novo* kidney transplant candidates who fulfilled all inclusion/exclusion criteria were randomized to receive either LCP-Tacro™ or Prograf® following their kidney transplantation. A 24-hour pharmacokinetic (PK) profile assessment was performed on Study Days 1, 7 and 14. Patients continued in the 50 weeks maintenance stage of the study to evaluate the long-term safety and efficacy of LCP-Tacro™ versus Prograf®.

For more information, please contact:

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About LCP-Tacro™ and tacrolimus

Tacrolimus is a leading immunosuppression drug used for the prevention of transplant allograft rejection after organ transplantation. LCP-Tacro™ is being developed as a once daily tablet version of tacrolimus, with improved bioavailability and reduced peak-to-trough variability when compared to Astellas Pharma's Prograf®, a twice daily version of tacrolimus, marketed world-wide, and its once daily version of tacrolimus, Advagraf®, marketed in some European countries. Transplant patients need to maintain a minimum blood level of tacrolimus for the prevention of transplant allograft rejection, but excessive levels may increase the risk of serious side effects such as nephrotoxicity and opportunistic infections. Therefore, tacrolimus levels need to be managed carefully, and transplant patients are typically obliged to make frequent visits to the hospital for monitoring and dose adjustments for months after receiving a new organ.

About LifeCycle Pharma A/S (LCP)

Based in Hørsholm, Denmark, with an office in New York, LCP is an emerging specialty pharmaceutical company. Clinical development is the core of LCP's efforts to develop a product portfolio which includes products for immunosuppression, specifically organ transplantation, and products to combat certain cardiovascular diseases. As a fully integrated company, LCP adapts new technologies on a fast commercial timetable. LCP's unique, patented delivery technology, MeltDose®, can improve absorption and bioavailability – at low-scale up costs – not only for a broad spectrum of drugs already on the market but also for new chemical entities. LCP has a cholesterol-lowering product, Fenoglide®, currently on the U.S. market and a diversified near and medium-term pipeline with four product candidates in clinical trials and a number of projects in preclinical development. LCP is listed on the NASDAQ OMX Copenhagen under the trading symbol (OMX: LCP). For further information, please visit www.lcpharma.com.