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LifeCycle Pharma Receives Special Protocol Assessment (SPA) from FDA for LCP-Tacro™ Pivotal Phase 3 Study in *De Novo* Kidney Transplant Patients

LifeCycle Pharma's pivotal Phase 3 3002 Study for LCP-Tacro™ will be initiated in 2010.

Hørsholm, Denmark, August 12, 2010: LifeCycle Pharma A/S (OMX: LCP) today announced receipt of agreement with the U.S. Food and Drug Administration (FDA) on a Special Protocol Assessment (SPA) of its pivotal Phase 3 study, Study 3002, for LCP-Tacro™ in patients, who have just received a kidney transplant ("*de novo*" transplant patients).

William Polvino, President & Chief Executive Officer of LifeCycle Pharma said, "The SPA Agreement for Study 3002 of LCP-Tacro™ is a very significant achievement for LCP. We have now received a formal green light from the FDA as to our proposed clinical study design and are now well-positioned to move forward with the study start. Further, we have achieved increased clarity on the costs and timing to regulatory approval. LCP re-affirms its expectations of a target NDA filing in the first quarter of 2013, and we anticipate study initiation in the third quarter of this year."

"The optimized and patent-protected formulation used in LCP-Tacro™ provides desirable once-daily dosing of tacrolimus and is intended to reduce the peak-to-trough variability in blood levels," added Dr. John Weinberg, Senior Vice President, Commercial Development and Strategic Planning. He continued, "We are optimistic that LCP-Tacro™ will provide important patient benefits compared to existing treatments, will be a valuable addition to the therapeutic regimens available to transplant physicians, and has significant market potential."

The LCP Study 3002 is a randomized, double-blind, multicenter study that will compare once-daily LCP-Tacro™ against the current market leading comparator, twice-daily Prograf® in *de novo* kidney transplant patients. A 12-month treatment period will be followed by a 12-month blinded extension. The primary endpoint of the study will be to demonstrate the non-inferiority of LCP-Tacro™, compared to Prograf®, on kidney graft function (biopsy proven acute rejection, graft failure, death, or loss to follow up) at 12 months. Secondary endpoints will include safety, tolerability and renal function assessments. The study will be conducted at approximately 75-100 transplant centers, primarily in the United States and Europe.

LCP has developed LCP-Tacro™ as an optimized version of the highly successful transplant drug, tacrolimus (branded Prograf®). Worldwide sales of Prograf® were about 2 billion USD in 2009 (IMS; all rights reserved).

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About Special Protocol Assessments

The Special Protocol Assessment (SPA) process is a procedure by which the FDA provides official evaluation and written guidance on the design and size of proposed protocols that are intended to form the basis for a new drug application (NDA). Final marketing approval depends on the results of efficacy, the adverse event profile and an evaluation of the benefit/risk of treatment demonstrated in the Phase 3 clinical program. The SPA agreement may only be changed through a written agreement between the sponsor of the clinical program and the FDA, or if the FDA becomes aware of a substantial scientific issue essential to product efficacy or safety.

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, consistent pharmacokinetic performance and reduced peak-to-trough variability when compared to currently approved tacrolimus products. 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 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 clinical stage product candidates 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.