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LifeCycle Pharma Initiates Phase II Clinical Trial of LCP-Tacro for the Treatment of Autoimmune

**Hepatitis** 

Hørsholm, Denmark, January 02, 2008; LifeCycle Pharma A/S (OMX: LCP) (the "Company" or "LCP"), an

emerging specialty pharmaceutical company, today announced that it has initiated a Phase II clinical

trial of LCP-Tacro for the treatment of autoimmune hepatitis ("AIH"), also referred to as chronic active

hepatitis, a disease which causes a person's body to reject its own liver. The clinical trial is expected to

enroll up to 60 patients in up to 12 centers throughout the US and Canada. The Company expects to

report top-line clinical trial results in the first half of 2009 (1H09).

"We are excited about participating in the first clinical trial of LCP-Tacro in patients with autoimmune

hepatitis (AIH)," said Gerald Y. Minuk, MD, Professor of Medicine & Pharmacology and Head of the

Section of Hepatology at the University of Manitoba Health Sciences Centre in Winnipeg. "It's

important that physicians have new options for the management of AIH and we think LCP-Tacro could

make a real difference in patients' lives."

The clinical trial is a phase II, open-label, multi-center, prospective, randomized study to evaluate the

efficacy, safety and tolerability of LCP-Tacro tablets given once daily vs. azathioprine ("AZA"), each in

combination with prednisone, for the treatment of AIH. Up to 60 patients will be randomized (1:1) to

receive treatment with LCP-Tacro + prednisone vs. AZA + prednisone.

The Company is pursuing LCP-Tacro for what could be the first FDA-approved drug indicated for the

treatment of AIH.

**About Autoimmune Hepatitis (AIH)** 

AIH is a form of hepatitis or liver disease in which the body's immune system attacks liver cells, causing

inflammation and a rejection of one's own liver. If untreated, the inflammation can lead to cirrhosis

(scarring and hardening) of the liver and eventually liver failure. AIH mainly affects women with a

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bimodal age distribution (10 - 30 y) and 40 - 50 y. However infants, young children and older adults are

also affected.

**AIH Current Standard of Treatment** 

AIH is currently treated with corticosteroids (usually prednisone or prednisolone) and azathioprine in

order to reduce the autoimmune reaction and inflammation. Nearly 25% of patients achieve only

partial remission with standard treatment or cannot tolerate AZA for various reasons. Disease relapse is

frequent after AZA is withdrawn. Other, newer, immunosuppressive drugs in clinical development, such

as tacrolimus, are showing promise for people who do not respond to this standard treatment.

About LifeCycle Pharma A/S ("LCP")

LCP is an emerging specialty pharmaceuticals company that, through innovative technologies, is able to

rapidly develop a portfolio of differentiated products to meet the unique needs of key therapeutic

markets and patient populations. This includes products for immunosuppression, specifically organ

transplantation, and to combat certain cardiovascular diseases. By using its unique and patented

delivery technology, MeltDose®, LCP is able to develop drugs with enhanced absorption and thereby

increased bioavailability. Currently, the Company has a diversified near- and medium-term pipeline,

including a product ready for US commercialization, five product candidates in clinical trials and three in

preclinical stages of development. LCP is listed on the OMX Nordic Exchange under the trading symbol

(OMX: LCP). For further information, please visit www.lcpharma.com.

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