Exelixis and Helsinn Sign Agreement for XL119 (becatecarin)

SOUTH SAN FRANCISCO, and LUGANO, Switzerland, June 13 /PRNewswire/ -- Exelixis, Inc. (Nasdaq: EXEL) and Helsinn Healthcare S.A. reached an agreement for the development of XL119 (becatecarin). Under the terms of the agreement, Helsinn will pay Exelixis an upfront payment of $4 million and additional milestones up to $21 million. In addition, Helsinn will assume the cost of the Phase III program going forward. In return, Exelixis has granted to Helsinn a world-wide, royalty-bearing license to XL119. Exelixis has retained rights to reacquire commercial rights to XL119 for North America, and will receive milestones and royalties on sales in the rest of the world.

"We are gratified that we have found an excellent partner for the development of XL119," said George A. Scangos, Ph.D., president and chief executive officer of Exelixis. "Helsinn is a high-quality company with experience in cancer drug development, as demonstrated by their successful development and licensing of Aloxi(R) to MGI Pharma. By combining our resources with those of an excellent European partner, we hope to make XL119 available to patients in need around the world. This agreement will free up substantial financial and product development resources, allowing Exelixis to focus on the Phase I and II trials for our internally developed pipeline. At the same time, we have structured this deal with rights to reacquire the commercial rights to XL119 for North America, which is our primary market. I believe that this is an excellent transaction and represents a win for both companies," said Dr. Scangos.

"Exelixis has a very strong scientific foundation and we are pleased to be in a partnership with such a company," said Enrico Braglia, Managing Director of Helsinn. "Through the development of XL119, we aim to create a new standard of care for patients with biliary tract cancers, a rare and aggressive form of cancer with a high medical need and very limited survival. While some existing therapies have been used off-label to treat this type of tumor, there is currently no drug therapy that has been approved by regulatory authorities for this indication. We believe that XL119 will offer a meaningful therapeutic benefit over currently used therapies and will become the therapy of reference for biliary tract cancer patients worldwide."

XL119 is currently in a multi-national Phase III clinical trial at approximately 50 centers in North America and Europe. The primary endpoint of the 600-patient trial is increased survival of patients with bile duct tumors treated with XL119 compared with the chemotherapy agents 5-fluorouracil (FU) and leucovorin. The trial is currently recruiting and enrolling patients as anticipated and is on track to be completed as planned. XL119 was granted the Orphan Drug designation in the USA on March 1, 2004.

Conference Call and Webcast

Exelixis' management will discuss this agreement and other business developments during a conference call beginning at 5:30 a.m. PDT / 8:30 a.m. EDT today, Monday, June 13, 2005. To listen to the discussion, please visit the Webcast section under

About Exelixis

Exelixis, Inc. is a leading genomics-based drug discovery company dedicated to the discovery and development of novel therapeutics across various disease areas. The company is leveraging its fully integrated gene-to-drug platform to fuel the growth of its proprietary drug pipeline. Exelixis' development pipeline covers cancer and metabolism and is comprised of the following compounds: XL784, initially an anticancer compound, which completed a Phase I clinical trial and is being developed as a treatment for renal disease; XL647, XL999 and XL880, anticancer compounds currently in Phase I clinical trials; XL820 and XL844, anticancer compounds for which INDs have been filed; XL184 a potential IND candidate for the treatment of cancer; and multiple compounds in preclinical development for diseases including cancer and various metabolic and cardiovascular disorders. Exelixis has established broad corporate alliances with major pharmaceutical and biotechnology companies including GlaxoSmithKline (GSK) and Bristol-Myers Squibb Company. Pursuant to a product development and commercialization agreement between Exelixis and GSK, GSK has the option, after completion of Phase IIa clinical trials, to elect to develop a certain number of compounds in Exelixis' product pipeline, which may include the cancer compounds identified in this press release (other than XL119), thus potentially triggering milestone payments and royalties from GSK and co-promotion rights by Exelixis. For more information, please visit the company's web site at http://www.exelixis.com.

About HELSINN HEALTHCARE

HELSINN HEALTHCARE SA is a privately owned pharmaceutical group with headquarters in Switzerland. Helsinn's core business is the licensing of pharmaceuticals in niche therapeutic areas. The company's business strategy is to in-license early-stage new chemical entities and complete their development from the performance of preclinical/clinical studies and CMC development to the attainment of market approvals in strategic markets (U.S. and Europe). HELSINN's products are eventually out-licensed to its marketing partners for distribution. The active pharmaceutical ingredients and the finished dosage forms are manufactured at HELSINN's cGMP facilities and supplied worldwide to its customers. For more information about HELSINN, please visit http://www.helsinn.com.

This press release contains forward-looking statements, including without limitation all statements related to Exelixis' potential to receive future payments related to the clinical development program for XL119, the potential success of the XL119 Phase III trial, the therapeutic and commercial potential of XL784, XL647, XL880, XL999, XL820, XL844 and XL184, other compounds in the Exelixis preclinical pipeline and its program in
metabolic diseases. Words such as "believes," "anticipates," "plans," "expects," "intend," "will," "slated," "goal" and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon Exelixis' current expectations. Forward-looking statements involve risks and uncertainties. Exelixis' actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, the ability of the company to successfully conduct the clinical trials for XL784, XL647, XL880, XL999, XL820 and XL844; the ability of the company to advance additional preclinical compounds into clinical development; the uncertainty of the FDA approval process; and the therapeutic and commercial value of the company's compounds. These and other risk factors are discussed under "Risk Factors" and elsewhere in our quarterly report on Form 10-Q for the quarter ended March 31, 2005 and other filings with the Securities and Exchange Commission. Exelixis expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in the company's expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based.

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SOURCE Exelixis, Inc.

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