Gloucester Pharmaceuticals Acquires Worldwide Development and Commercialization Rights to Novel Anti-Cancer Compound from Fujisawa

- Novel HDAC Inhibitor is in Phase II clinical studies for hematologic and solid tumor indications -

Cambridge, MA and Osaka, Japan – April 15, 2004 - Gloucester Pharmaceuticals, Inc., a privately held cancer therapeutics development company, and Fujisawa Pharmaceutical Co., Ltd., one of Japan’s top pharmaceutical companies, announced today that Gloucester has acquired from Fujisawa an exclusive worldwide license to develop and commercialize Fujisawa’s novel histone deacetylase inhibitor (HDAC), known as FK228, as an anti-cancer agent. FK228 (depsipeptide) is currently in Phase 2 clinical trials for the treatment of renal cell carcinoma and hormone refractory prostate cancer. FK228 is also being studied in separate Phase 2 clinical trials for the treatment of cutaneous T-cell lymphoma, as well as other indications by the National Cancer Institute (NCI) under a Cooperative Research and Development Agreement (CRADA) with Fujisawa.

Under the terms of the license agreement, Fujisawa will receive an upfront licensing fee, in addition to R&D and commercialization milestone payments and royalties on net sales.

“The licensing of FK228 is an important first step in validating our business model to build a franchise of new cancer therapeutics,” said Jay Mohr, President and CEO of Gloucester. “Our licensing strategy is to obtain novel compounds that, either as monotherapy or in combination with other therapies, can have a profound effect in the treatment of many hematologic and solid tumors. We believe that FK228 has such potential and we are very pleased to have an opportunity to develop a first-in-class HDAC inhibitor.”

“We have been very impressed by Gloucester’s experienced management team and their capabilities to develop FK228 as an anti-cancer agent,” stated Hirofumi Onosaka, Corporate Vice President, Global Corporate Strategic Planning of Fujisawa. “We believe that Gloucester is well positioned to realize the full commercial potential of FK228 as an anti-cancer compound – one that fits perfectly into their business strategy.”
About FK228

FK228 is one of a new class of anti-cancer agents known as histone deacetylase (HDAC) inhibitors. It has been demonstrated in numerous preclinical studies performed by Fujisawa and others, that the inhibition of histone deacetylation, which is instrumental in the regulation of gene expression, causes cell cycle arrest, differentiation and apoptotic cell death. Due to the mechanism of action of HDAC inhibition, HDAC inhibitors are thought to have the potential for improved efficacy over traditional cytotoxic agents.

Upon the execution of this license agreement, Gloucester assumed control over the company-sponsored, ongoing Phase 2 studies with FK228 as monotherapy for the treatment of renal cell carcinoma and hormone refractory prostate cancer. Additionally, Fujisawa will, subject to consent of the NCI, transfer and assign to Gloucester its obligations under the ongoing CRADA. Under the CRADA, FK228 is currently being studied in Phase 2 clinical trials for the treatment of cutaneous T-cell lymphoma. FK228 is also being investigated under the CRADA with NCI, as both monotherapy and in combination therapy, in Phase 1 and Phase 2 trials for other hematologic and solid tumor indications.

About Gloucester Pharmaceuticals, Inc.

Gloucester Pharmaceuticals, Inc. is a privately held, venture-backed company that develops and commercializes innovative products for the treatment of cancer. The company employs an in-licensing strategy to build a diversified product portfolio to address the significant unmet medical need in the management of cancer. Gloucester is headquartered in Cambridge, Massachusetts and is backed by Apple Tree Partners, an early stage life sciences venture fund with over $105 million under management. For more information visit www.gloucesterpharma.com.

About Fujisawa Pharmaceutical Co., Ltd.

Founded in 1894, Fujisawa Pharmaceutical Co., Ltd. looks back on a history of over 100 years that have seen the Company develop into one of the leading pharmaceutical manufacturers in Japan. The Company forms the core of the Fujisawa Group, which now has offices, plants and research facilities in Japan, North America, Europe and Asia with more than 8,000 employees worldwide. As a research-driven pharmaceutical company, Fujisawa’s research and development activities are the key to its success in the highly competitive global market.
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