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Peregrine Pharmaceuticals Announces Patent Grant for Vasopermeation Enhancement Technology

TUSTIN, Calif., May 19 /PRNewswire-FirstCall/ -- Peregrine Pharmaceuticals (Nasdaq: PPHM) announced today the issuance of U.S. Patent No. 6,737,064, entitled "Method for the diagnosis of neoplastic tissue comprising administering a vasopermeability enhancing peptide of human interleukin-2," which covers methods for using a portion of the cytokine interleukin-2 known as Permeability Enhancing Peptide (PEP) to enhance the diagnosis of cancer. The PEP technology has been exclusively licensed to Peregrine and is part of its Vasopermeation Enhancement Agents (VEA) technology platform which is used to enhance existing cancer therapeutic and diagnostic agents.

"These new method claims extend our coverage to use VEAs for enhancement of diagnostic agents," said Steve King, Peregrine's president and CEO. "We believe there is a significant commercial potential for VEA agents and this patent is a valuable addition to the VEA patent portfolio."

In published reports, scientists have seen an almost 400% increase in the normal amount of chemotherapeutic agent taken up by solid tumors with a VEA pre-treatment. In pre-clinical studies, Peregrine's VEA technology has been shown to significantly improve the effectiveness of chemotherapeutic agents including Doxorubicin, Taxol, Vinblastine, VP-16 and Taxotere in tumor therapy experiments. Data related to the VEA technology platform has been published in a number of peer reviewed journals, including, most recently, the "Journal of the National Cancer Institute" and the technology has been reviewed in "Lancet Oncology" and "Nature Reviews Cancer."

Peregrine's primary research focus is to develop agents that act on tumor blood vessels for therapeutic and diagnostic purposes. VEAs are agents that make tumor blood vessels selectively leaky, allowing more of an administered therapeutic or diagnostic agent to reach the tumor. Peregrine is currently evaluating VEAs that utilize its human TNT targeting platform linked to the PEP molecule as pre-clinical candidates which may make it possible to use a single VEA as a pre-treatment for a variety of different tumor types and chemotherapeutic agents. Additional information regarding Peregrine's VEA program and other useful information can be found on Peregrine's recently released website at http://www.peregrineinc.com.

About Interleukin-2

Of the numerous biological molecules currently under consideration for development as cancer therapeutics, few have been as severe in side effects as interleukin-2 (IL-2). IL-2 is a naturally occurring cytokine, which is produced by helper T lymphocytes. Cytokines are proteins in the body that stimulate and regulate the immune system. IL-2 is an important cytokine and occupies a central role in the augmentation of cell-mediated immune response. In addition to its cytokine activity, IL-2 has been shown to contain a domain which produces vascular permeability when administered systemically. This phenomenon is known as vascular leak syndrome (VLS). When IL-2 is used in a clinically effective dose for the treatment of cancer, it causes massive leaking of blood, fluids and serum proteins from the vascular network resulting, eventually, in organ failure. This toxic side effect has limited the clinical effectiveness of IL-2 for the treatment of cancer.

About Permeability Enhancing Peptide

The goal of Peregrine's research on IL-2 was to develop a drug compound that had the ability to induce vascular leak syndrome at, and only at, the tumor site. To achieve this, scientists at the University of Southern California identified the region of IL-2 that is responsible for causing vascular leak syndrome. This region was then synthesized and tested for suitability as a vasopermeability agent. Preclinical studies showed this region has 100% of the vasopermeability activity of intact IL-2 but lacked its cytokine activity. This proprietary new compound is called Permeability Enhancing Peptide (PEP) and Peregrine has exclusively licensed it from the University of Southern California. By attaching PEP to a monoclonal antibody (MAB) that targets tumors, Peregrine's scientists are able to localize vascular leak syndrome only at the tumor site.

About Vasopermeation Enhancement Agents

Barriers to Existing Cancer Therapies

Drugs that target cancer cells must overcome a significant number of structural barriers within the tumor in order to be effective. They must first exit the tumor blood vessels, migrate past the support structures that underlie the vessels and

eventually make their way to the cancer cells. As a result of these structural barriers, very little drug injected into the blood stream of a patient is able to reach and destroy cancer cells. One potential solution to this problem is to increase the permeability of the blood vessels within the tumor which will permit more therapeutic drug to reach and kill substantially more cancer cells.

Mechanism of Action

Vasopermeation Enhancement Agents (VEAs) are a class of drugs which are designed to increase the uptake of cancer therapeutics and imaging agents at the tumor site, resulting in greater efficacy. VEAs work by using monoclonal antibodies (MABs) to deliver known vasoactive compounds (i.e. molecules that cause tissues to become more permeable) selectively to solid tumors. Once localized at the tumor site, VEAs alter the physiology and the permeability of the vessels and capillaries that supply the tumor. In pre-clinical studies, VEAs have improved drug uptake up to almost 400% in solid tumors. VEAs may be used as either pre-treatments or potentially as part of the therapeutic molecule for therapy and imaging of cancer.

About Peregrine Pharmaceuticals, Inc.

Peregrine's research and development efforts focus on discovering and developing products that affect blood flow to tumors. Peregrine's vascular research programs fall under several different proprietary platforms including Anti-Phospholipid Therapy (APT), Vascular Targeting Agents (VTAs), anti- Angiogenesis and Vasopermeation Enhancement Agents (VEAs). The company has research collaborations with pharmaceutical and biotechnology companies to develop its VTA platform for therapeutic and diagnostic applications and expects to enter its first APT compound into clinical trials for cancer therapy during calendar year 2004.

Peregrine's vascular agents may also have applications in other angiogenesis-dependent diseases besides cancer such as diabetes, arthritis, skin disorders and eye diseases. Peregrine currently has exclusive rights to over 190 U.S. and foreign patents and patent applications that broadly cover its vascular programs. In addition, the company is currently evaluating its proprietary technology for use in treating non-angiogenesis dependent diseases such as viral infections. The company believes that the pre-clinical data generated by the company and the broad nature of its intellectual property may provide many opportunities for product development, partnering and licensing.

Peregrine's most clinically advanced therapeutic program is based on a targeting platform outside vascular biology. This technology platform is known as Tumor Necrosis Therapy (TNT) and targets dead or dying tumor cells that are common to the majority of different tumor types. Cotara™, the most clinically advanced TNT program, is currently in a Phase I clinical trial for the treatment of colorectal carcinoma at Stanford University Medical Center. In addition, we have received protocol approval from the U.S. Food and Drug Administration ("FDA") to initiate a registration clinical study for the treatment of brain cancer. The company is currently seeking a development or funding partner to move the brain cancer program forward. The company believes that continuing the clinical development of Cotara™ in tumor types other than brain cancer will add significant value t the program. The company has a research collaboration to develop immunocytokines based on the TNT platform and a TNT based agent has been developed and approved for the treatment of lung cancer in China under a licensing agreement.

The company also operates a cGMP contract manufacturing facility for monoclonal antibodies and recombinant proteins through its wholly owned subsidiary Avid Bioservices, Inc. (www.avidbio.com). Avid produces clinical trial materials to support phase I through phase III clinical trials for biotechnology companies including Peregrine. Copies of Peregrine press releases, SEC filings, current price quotes and other valuable information for investors may be found on the website http://www.peregrineinc.com.

Safe Harbor Statement: This release may contain certain forward-looking statements that are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Actual events or results may differ from the company's expectations as a result of risk factors discussed in Peregrine's reports on file with the U.S. Securities and Exchange Commission, including, but not limited to, Peregrine's report on Form 10-Q for the quarter ended January 31, 2004 and on Form 10-K for the year ended April 30, 2003.

SOURCE Peregrine Pharmaceuticals, Inc.
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