Hemispherx Biopharma RNA Drug Technology Targets New Molecular Defects Uncovered in Prostate Cancer

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National Human Genome Research Pinpoints First Specific Gene Which Confers High Risk for Prostate Cancer

Prostate 'Cancer Susceptibility Gene' is New Therapeutic Target

Philadelphia, PA, Monday, November 04, 2002: -- Hemispherx Biopharma, Inc. (Amex: HEB) reported today that its RNA-based drug technology has immediate potential as the first specific therapy for a new genetically based prostate cancer pinpointed by the National Human Genome Research Institute, National Institutes of Health (NIH). Collaborating institutions, including more than 15 academic medical centers in the U.S. and Europe, reported on patients with prostate cancer and their family members. A recent Nature scientific journal expands on these findings.

Background

Although prostate cancer is the most common non-cutaneous malignancy diagnosed in men in the United States, very little has been known about inherited factors that influence its genetic disposition. Much better knowledge exists, for example, regarding causes of breast and ovarian cancers. The aggressive form of prostate cancer kills more than 30,000 Americans per year.

New Diagnostic Finding and Therapeutic Implications for RNA-based Drugs

NIH said (Nature Genetics, vol. 30, 2002) that hereditary prostate cancer is associated with a critical new defect in a mediator (e.g. bodily defense) substance called "RNase L". RNase L is a natural antiviral material commonly activated by exposure of the body to certain types of RNA (ribonucleic acid), called ds (double-stranded) RNA. DsRNA usually appears when viruses begin multiplying in the human body as part of the general immune response alarm signal to ward off infection. A high percentage of prostate cancer cases demonstrated the defect in the RNase L alarm signal. In contrast, no defects were seen in 698 control (or normal) individuals, of which 284 controls were African Americans, a group predisposed to prostate cancer. The NIH study concludes "these findings on ... germline mutations in this gene [RNase L] could lead to early diagnosis and therapeutic approaches for prostate cancer ... ."

Prostate Cancer Spread

Data presented in follow-on studies at the University of Michigan indicate that, as the prostate cancer spreads, or metastasizes, up to 55 growth controlling genes are turned on and render an even deadlier form of the disease. Thus, it appears potentially very important to identify, and correct if possible, the underlying initial gene defect - RNase L - as quickly as possible.

Present State of Prostate Cancer Therapy and Prevention

Present prostate cancer therapy is not based on specific genetic alterations that lead to the cancer. Therapeutic success is often limited in magnitude, significant side effects are observed, and benefits are generally of short duration. Similarly, prevention is limited to general dietary measures which may increase overall dietary quality (including dietary supplementation in anti-carcinogenic food products) but without any specificity for protecting the prostate gland.

Present State of RNA-directed Immune Defense Mediators in Human Disease

Hemispherx has evolved as a world leader in creating new experimental drug modalities which may operate at the RNase L level. This technology is protected by nearly 400 patents worldwide. In addition, Hemispherx is presently conducting Phase III Clinical Studies in Chronic Fatigue Syndrome and Phase IIb studies in HIV/AIDS. These diseases were selected for clinical development because of the dysfunction in RNase L. Company scientists reasoned that these defects might create a favorable environment for the development of chronic viral infection and therefore needed to be corrected to achieve potential therapeutic outcomes. The Company has also conducted studies in Hepatitis B, another chronic viral infection associated with RNase L antiviral/immunodefense abnormalities. The new clinical studies, prostate studies, in individuals with prostate cancer and /or at high risk to its development, suggest that this same immunological pathway, when unbalanced, may also create a favorable environment for the development of prostate cancer.

About Hemispherx

Hemispherx Biopharma, based in Philadelphia, is a bio-pharmaceutical company engaged in the manufacture and

global clinical development of new drug entities in the nucleic acid (NA) class for chronic viral diseases and disorders of the immune system including, HIV, CFS and Hepatitis. Its platform technology includes large and small agent components for potential treatment of various chronic viral infections. For more information visit the company's Web site at www.hemispherx.net.

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