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STRESSGEN PRESENTS POSITIVE CLINICAL DATA AT 18TH INTERNATIONAL PAPILLOMAVIRUS CONFERENCE

HspE7: A Novel Heat Shock Protein Fusion for HPV-Related Diseases

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BARCELONA, SPAIN – StressGen Biotechnologies (SSB:TSE) announced today that preliminary Phase II data presented at the 18th International Papillomavirus Conference held this week in Barcelona demonstrate activity of HspE7, a novel immunotherapeutic, in the treatment of HPV-related anal dysplasia. The Company also reported new data on HspE7's mechanism of action, as well as data from a healthy volunteer trial.

HPV infects approximately 30% of the sexually active population, with 24 million already infected in the US alone. This virus is responsible for anal and cervical dysplasias which can precede the development of anal and cervical cancer.

"These data establish clinical proof of principle for HspE7 as an important therapeutic for HPV-related diseases, one example of which is anal dysplasia" said Dr. John Neefe, VP Clinical and Regulatory Affairs at StressGen.

StressGen's Phase II AIN trial is a randomized, double blind, placebo-controlled trial of 3 monthly subcutaneous doses of 100 mcg (micrograms) of HspE7 conducted in patients with biopsy-proven anal high grade squamous intraepithelial lesions (HSIL). Patients with persistent HSIL in biopsy specimens taken 1 month after completing 3 injections are permitted to cross over to an open label trial of 3 doses of 500 mcg of HspE7. Results from the randomized trial remain blinded, but the first data from the open label trial were reported at the Conference. Additional data from the open label trial, when available, will be presented in the appropriate medical forum. A phase III randomized, double blind, placebo-controlled study is planned to corroborate the clinical observations from the open label anal dysplasia trial.

The first eight consecutive patients entered into the open label trial of 3 doses of 500 mcg of HspE7 were seven men and one woman with high grade anal dysplasia (HSIL). After 3 injections of HspE7, all had evidence of clinical response determined colposcopically, and the physician's global assessment of clinical benefit improved by 65% to 95%. For all 8, the surgical procedure that would have been recommended for clearance of lesions became less extensive and/or less invasive. Pathologically, the dysplasia was improved in all patients.

"The medical community is just beginning to understand the full impact of AIN, and treatment recommendations are evolving. Most patients require some form of ablative treatment, but the procedure required can be painful and debilitating. New therapies are badly needed, and the HspE7 clinical data appear to be a promising development," said Dr. Stephen Goldstone, MD, a surgeon and AIN specialist who reported the results at the Conference.

Dr. Goldstone continued, "Since the abstract was written in June, I have evaluated the next two consecutive patients. Each responded in a fashion similar to the first eight."

The data from the two other presentations at the Conference supporting these conclusions include:

- HspE7 induces proliferative T cell responses to HPV 16 E7 peptides in healthy volunteers.

- Presentation and processing of the HspE7 fusion protein by the immune system results in the production of cytokines associated with the induction of a cellular immune response. This report is consistent with preclinical data which will appear in the journal *Clinical and Experimental Immunology* in August, 2000.

StressGen Biotechnologies Corporation is a biopharmaceutical company focused on the development and commercialization of innovative stress protein-based immunotherapeutics. The Company has an active phase II HspE7 study in women with high-grade cervical dysplasia and plans to initiate a phase II HspE7 trial for cervical cancer as well as a phase III AIN trial. In addition, StressGen will be expanding the HspE7 clinical program to include genital warts. The Company is developing a broad range of stress protein-based therapeutic products for the treatment of virally induced infections and cancers. StressGen has also initiated studies to evaluate the technology in asthma and allergy. Through its Biochemical Division, StressGen is also an internationally recognized supplier of research products for the study of cellular stress, apoptosis, oxidative stress and neurobiology. These products are used by scientists worldwide.

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