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Peregrine Pharmaceuticals Presents Preclinical Data Demonstrating PS-Targeting Antibodies Significantly Enhance the Anti-Tumor Activity of Multiple Checkpoint Targeting Agents in Model of Triple Negative Breast Cancer (TNBC)

-- Complete Tumor Regression Seen in 80% of Animals Treated with Triple Combination of PS-Targeting Antibody, Anti-PD-1 Therapy and Anti-Lag3 Therapy vs. 0% of Animals Receiving Double Anti-PD-1/Anti-Lag3 Treatment Combination --

-- Triple Combination Shows Statistically Significant Increases in Key Tumor Fighting Immune Cells and a Reduction in Immunosuppressive Immune Cells vs. Anti-PD-1/Anti-Lag 3 Combination Therapy --

TUSTIN, Calif., Sept. 27, 2016 (GLOBE NEWSWIRE) -- Peregrine Pharmaceuticals, Inc. (NASDAQ:PPHM) (NASDAQ:PPHMP), a biopharmaceutical company committed to improving patient lives by manufacturing high quality products for biotechnology and pharmaceutical companies and advancing its proprietary R&D pipeline, today announced the presentation of preclinical study data demonstrating that phosphatidylserine (PS)-targeting antibodies similar to bavituximab are able to enhance the anti-tumor activity of multiple checkpoint targeting agents including anti-PD-1 and anti-LAG3 therapies in a model of triple negative breast cancer (TNBC). Data showed that eight of the ten (80%) animals receiving the preclinical bavituximab equivalent (ch1N11) combined with anti-PD-1 and anti-LAG3 therapies ("Triple Combination") experienced complete tumor regressions, whereas there were no animals (0/10) in the anti-PD-1 and anti-LAG3 combination treatment arm that had a complete regression.

Additional data demonstrated that the Triple Combination featuring ch1N11 led to a 99% reduction in total tumor volume at the interim analysis point (Day 25) across all animals as compared to the control arm. In addition, the Triple Combination showed a statistically significant increase in tumor growth inhibition (TGI) as compared to the anti-PD-1 and anti-LAG3 combination treatment (99% vs. 62%; $p < 0.05$). Peregrine's Michael J. Gray, Ph.D., the study's lead scientist, presented the study findings at the Second CRI-CIMT-EATI-AACR International Cancer Immunotherapy Conference September 25-28, 2016, in New York City.

The presented study evaluated various combinations of ch1N11, anti-PD-1 and anti-LAG3 therapy in the well-characterized E0771 murine model of TNBC. Other key study findings included:

- Treatment with Triple Combination therapy (ch1N11/anti-PD-1/anti-LAG3) led to a significant increase in tumor infiltrating lymphocytes (TILs), particularly CD8+ T cells, as compared with anti-PD-1 and anti-LAG3 combination treatments.
- Treatment with Triple Combination therapy (ch1N11/anti-PD-1/anti-LAG3) resulted in a reduction in immunosuppressive cell types, including CD4+ cells, regulatory T cells (Tregs) and myeloid derived suppressor cells (MDSCs). These results show that the Triple Combination therapy is capable of significantly altering the tumor microenvironment from highly immunosuppressive to highly immuno-stimulatory. Other treatment combinations evaluated in the study lacked a statistically significant reduction in immunosuppressive cells.

"These data offer compelling evidence for the therapeutic potential of including PS-targeted therapies in combination with multiple checkpoint inhibitors in the treatment of TNBC. This is highlighted by the dramatic distinction in complete tumor regression rates seen between the Triple Combination and anti-PD-1/anti-LAG3 treatment arms, combined with the significant difference in tumor growth inhibition percentages witnessed for these groups," stated Jeff T. Hutchins, Ph.D., Peregrine's vice president, preclinical research. "In addition to its impact on tumor growth, we saw very important changes in the tumor microenvironment with the Triple Combination treatment with a significant reduction in cell types that contribute to immune suppression such as $CD4^+$ cells, Tregs and MDSCs coupled with the expansion of tumor fighting cells such as CD8+ T cells. These data offer mechanistic evidence that highlight the manner by which the combination of ch1N11/anti-PD-1/anti-LAG3 may be eliciting such anti-tumor responses."

Bavituximab is an investigational monoclonal antibody that targets PS. Signals from PS inhibit the ability of immune cells to recognize and fight tumors. Bavituximab is believed to override PS mediated immunosuppressive signaling by blocking the engagement of PS with its receptors as well as by sending an alternate immune activating signal. Previous studies demonstrated PS-targeting antibodies shift the functions of immune cells in tumors, resulting in multiple signs of immune

activation and anti-tumor responses. Peregrine evaluates the preclinical equivalent of bavituximab, ch1N11, in animal model studies to guide clinical development.

Peregrine's clinical development strategy for bavituximab currently focuses on small, early-stage, proof-of-concept trials evaluating the drug in combination with other cancer treatments. This approach includes the recently announced grants by the National Comprehensive Cancer Network (NCCN) to support three different clinical trials of bavituximab treatment combinations. Those trials will evaluate novel bavituximab combinations in glioblastoma, head and neck cancer, and hepatocellular carcinoma including an immunotherapy combination. Additionally, Peregrine continues to advance its pre-clinical collaboration with Memorial Sloan Kettering Cancer Center with the goal of evaluating combinations of bavituximab with other checkpoint inhibitors and immune stimulatory agents. The intent behind this strategy is to focus our research and development spending to further validate bavituximab's combination potential as we seek to advance the program though a pharmaceutical or biotechnology partner.

About Peregrine Pharmaceuticals, Inc.
Peregrine Pharmaceuticals, Inc. is a biopharmaceutical company committed to improving the lives of patients by delivering high quality pharmaceutical products through its contract development and manufacturing organization (CDMO) services and through advancing and licensing its investigational immunotherapy and related products. Peregrine's in-house CDMO services, including cGMP manufacturing and development capabilities, are provided through its wholly-owned subsidiary Avid Bioservices, Inc. (www.avidbio.com), which provides development and biomanufacturing services for both Peregrine and third-party customers. The company is also working to evaluate its lead immunotherapy candidate, bavituximab, in combination with immune stimulating therapies for the treatment of various cancers, and developing its proprietary exosome technology for the detection and monitoring of cancer. For more information, please visit www.peregrineinc.com.

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