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New Study Demonstrates Anti-Tumor Advantages for Combination Treatment Featuring Peregrine Pharmaceuticals' PS-Targeting Antibodies in a Preclinical Melanoma Model

-- Promising Results of MSK Study Evaluating Combinations of PS-Targeting Treatment, Anti-PD-1 and Radiation in Mouse B16 Melanoma Model Presented at SITC 2016 --

-- New Data from Second Study Conducted by Peregrine Shows Triple Combination of PS-Targeting Treatment, Anti-PD-1 and Anti-LAG3 Created Long-Term Immunity in Triple Negative Breast Cancer Model; Protected Animals when Re-Challenged with Breast Cancer Cells --

TUSTIN, Calif., Nov. 14, 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 positive data from multiple new preclinical studies of the company's phosphatidylserine (PS)-targeting antibodies. Study results highlight that PS-targeting antibodies similar to bavituximab synergize with checkpoint inhibitors and radiation to improve anti-tumor activity in various animal tumor models. Importantly, the improved anti-tumor activity seen in these studies was even greater when PS-targeting therapy was a part of triple combination treatment including anti-PD-1 and another therapy. Data were presented by Peregrine scientists, as well as researchers from Memorial Sloan Kettering Cancer Center (MSK), at the Society for Immunotherapy of Cancer (SITC) 2016 Annual Meeting, which was held November 9-13, 2016 in National Harbor, MD.

Initial results from Peregrine's ongoing collaboration with MSK researchers were featured in a poster presented by Sadna Budhu, Ph.D., at SITC 2016. A team of MSK researchers led by cancer immunotherapy thought-leaders, Taha Merghoub, Ph.D. and Jedd D. Wolchok, M.D., Ph.D., evaluated the effects of combining PS-targeting, anti-PD-1 and radiation therapies in the mouse B16 melanoma model. Study data showed that PS-targeting antibodies synergize with both anti-PD-1 and radiation therapy to improve anti-cancer activity. PS-targeting treatment in combination with radiation, as well as triple combination of PS-targeting treatment, anti-PD-1 and radiation, led to a reduction in tumor burden. Median survival for the triple combination treatment still had not been reached at the end of the 80-day observation period with other arms in the study showing median survival that ranged from 24-70 days.

Researchers also evaluated the impact of the PS-targeting and radiation combination treatment on the level and type of immune activity. These results demonstrated that the combination led to a change in the tumor microenvironment, shifting it from immunosuppressive in which tumors are protected to immune active in which tumors are more susceptible to treatment. Analysis of local immune responses in the tumors of the treated animals showed that the combination treatment increased the number of tumor associated macrophages and shifted the macrophage polarization from the immunosuppressive M2 type to the immune active M1 type. When systemic immune responses were analyzed following triple combination of PS-targeting treatment, anti-PD-1 and radiation, researchers also saw evidence of increased immune activity. This was illustrated by key indicators of immune activity, including increases in CD8+ T-cell activation, effector cytokine production and differentiation into effector memory cells.

"Based on these study results, we believe that the targeting of PS is having meaningful activity within the tumor microenvironment in the B16 melanoma model," stated Dr. Wolchok. "It appears that this activity creates a more immune active environment in which other treatments, including radiation, are able to have a greater anti-tumor impact."

"We have noted that the combination of PS-targeting treatment and radiation, as well as triple combination of PS-targeting treatment, radiation and anti-PD-1, resulted in clear advantages in anti-tumor activity in the mouse B16 melanoma model," said Taha Merghoub, Ph.D., co-director of the Ludwig Collaborative Laboratory at MSK. "We believe that these findings suggest the potential benefit of combining these agents to improve the outcomes of patients with cancer. With this in mind, we think this research may play an important role in designing future clinical trials of PS-targeting agents in melanoma and other cancers."

A second study, conducted by Peregrine, evaluated the effects of combining PS-targeting, anti-PD-1 and anti-LAG3 therapies in the E0771 triple negative breast cancer (TNBC) model. Initial findings from this study were previously reported and demonstrated that eight of the ten (80%) animals receiving the PS-targeting, anti-PD-1 and anti-LAG3 treatment 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. New data presented for the first time at SITC demonstrated that the triple combination established a specific and prolonged anti-tumor immune response which protected those eight animals that achieved a complete tumor regression against a re-challenge with the same E0771 TNBC model tumor cells. This sustained anti-tumor response demonstrates the ability of the triple combination treatment to trigger immune system memory and support adaptive immune responses against reemerging disease in the E0771 TNBC model.

Further highlighting the immune impact of the PS-targeting/anti-PD-1/anti-LAG3 treatment combination were initial results of a new analysis from this study using the nCounter® PanCancer Immune Profiling Panel from NanoString Technologies®. Data from the analysis demonstrated that the triple combination induced a greater shift in the tumor microenvironment from immunosuppressive to immune active as compared to all other treatment groups. This was evidenced by greater increases in the activity of several critical immune activating pathways, including presentation and processing of antigens and signaling and activation of T-cells, for the triple combination as compared to all other treatments.

"It is very encouraging to see the consistent increase in anti-tumor activity triggered by triple combination treatments that combine PS-targeting agents and anti-PD-1 with other cancer treatments. By demonstrating this activity across multiple studies in multiple tumor models, we are continuing to build scientific support for the therapeutic potential of adding PS-targeting therapies in combination with other cancer treatments, including checkpoint inhibitors such as anti-PD-1," said Jeff T. Hutchins, Ph.D., Peregrine's vice president, preclinical research. "As cancer research continues to explore the potential of combination treatments that marry complementary mechanisms, we are pleased to see that our efforts continue to generate data supporting the role that PS-targeting agents such as bavituximab may play in this area."

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 continues to support and guide clinical development through the evaluation of the preclinical equivalent of bavituximab, ch1N11, in animal model studies.

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 awarded by the National Comprehensive Cancer Network (NCCN) to support three different clinical trials of bavituximab treatment combinations. These 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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