

AZ, Peregrine expand ongoing Immuno-Oncology collaboration

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Peregrine Pharmaceuticals has announced that it has expanded its ongoing cancer immunotherapy clinical collaboration with AstraZeneca to include a second, later-stage trial. The companies will now also evaluate the immunotherapy combination of Peregrine's phosphatidylserine (PS)-targeted immune-activator, bavituximab, and AstraZeneca's anti-PD-L1 immune checkpoint inhibitor, durvalumab (MEDI4736), in a global Phase II study in patients with previously treated squamous or non-squamous non-small cell lung cancer (NSCLC). The randomized Phase II trial will be conducted by Peregrine.

As part of the Phase II bavituximab and durvalumab combination trial, patients will be evaluated retrospectively for the correlation between their PD-L1 levels and clinical outcomes. This new study builds on the non-exclusive collaboration initiated between the companies in August 2015 to conduct a Phase I/Ib basket clinical trial evaluating the combination of bavituximab and durvalumab with chemotherapy in multiple solid tumors.

Bavituximab and durvalumab are investigational immunotherapies with different mechanisms that assist the body's immune system in fighting cancer. Bavituximab targets and modulates the activity of phosphatidylserine, a highly immune-suppressive molecule expressed broadly on the surface of cells in the tumor microenvironment. In pre-clinical and translational clinical studies, the treatment increases activated T-cells in tumors and fights cancer by reversing the immunosuppressive environment that many tumors establish in order to proliferate. Durvalumab is a monoclonal antibody directed against programmed cell death ligand 1 (PD-L1). Signals from PD-L1 help tumors avoid detection by the immune system. Preclinical data have demonstrated that combining the enhanced T-cell mediated anti-tumor activity of bavituximab with checkpoint inhibitors, like PD-L1 antibodies, prolong the ability of tumor-specific T-cells to continue attacking the tumor.

"In the short period of time that we have been working with AstraZeneca, we have been very impressed with the company's commitment to innovative translational efforts that will help us better understand the dynamics of tumor immunity and clinical response to durvalumab and bavituximab combination in a range of cancers," said Mr Joseph Shan, vice-president, clinical and regulatory affairs of Peregrine. He added, "We expect this extension of our collaboration with AstraZeneca will allow us to

run a much more cost-effective and time-efficient trial than would have been possible under our previously planned study using Opdivo as the combination drug in the same lung cancer population. This Phase II study offers several key advantages including a supply of durvalumab that will enable us to conduct a global trial that can enroll patients more rapidly. In addition, the expanded collaboration provides for a more cohesive clinical program utilizing the same PD-L1 and other biomarker analysis across both the new Phase II trial and the already planned Phase I/Ib study combining durvalumab and bavituximab in multiple indications."