

Paloma Pharmaceuticals Update on Ocular Clinical and Oncology Programs

-- Through first three cohorts of intravitreal macular degeneration Phase I trial, start of National Eye Institute subconjunctival macular degeneration Phase I trial, publication/submission of cancer studies, presentation at AACR "Targeting PI3K/mTOR Signaling in Cancer" --

Jamaica Plain, MA, 1 March 2011 -- Paloma Pharmaceuticals, Inc. announced today updates on its age-related macular degeneration Phase I trials and oncology program. Palomid 529 (P529), Paloma Pharmaceuticals first-in-class allosteric dual TORC1/TORC2 dissociative inhibitor targeting the PI3K/Akt/mTOR pathway, has successfully completed the Company's first three cohorts of its Phase I intravitreal administration trial in patients with age-related macular degeneration (AMD). In addition, the National Eye Institute has treated its first patient in the Institute's own Phase I AMD trial administering P529 subconjunctival, "A Phase I Unmasked Study to Investigate the Safety and Tolerability of Subconjunctival Injections of Palomid 529 in Patients With Neovascular Age-Related Macular Degeneration." Both clinical trials have shown preliminary activity.

"Relative to our oncology program, we have now completed oral formulation work to ultimately deliver P529 as a tablet. This final step puts us close to submitting our oncology IND package to the FDA. Furthermore, we have now shown activity of P529 in difficult to treat tumors with Brca-1 and PTEN mutations with two newly published manuscripts," said Dr. Sherris.

"Targeting the Akt/mTOR pathway in Brca1-deficient cancers" was published in the Nature journal Oncogene from the laboratory of Qin Yang, M.D., Ph.D. of the Department of Radiation Oncology, Washington University School of Medicine, St. Louis, MO. "Palomid 529 significantly suppressed Brca1-deficient tumor growth in mice through inhibition of both Akt and mTOR signaling. Our results indicate that activation of Akt is involved in Brca1- deficiency mediated tumorigenesis and that the mTOR pathway can be used as a novel target for treatment of Brca1-deficient cancers," said Dr. Yang.

"The TORC1/TORC2 inhibitor, Palomid 529, reduces tumor growth and sensitizes to docetaxel and cisplatin in aggressive and hormone refractory prostate cancer cells" was published in the journal Endocrine-related Cancer from the laboratory of Claudio Festuccia, Ph.D. of the Department of Experimental Medicine, University of L'aquila, Italy. "The activation of PI3K/Akt/mTOR pathways is often observed during prostate cancer progression. Our studies provide preclinical evidence that the inhibition of this pathway is a very effective approach to treat hormone refractive prostate cancer. Here, the PI3K/Akt/mTOR pathway was targeted by using P529, an orally available TORC1/TORC2 inhibitor and showed that this agent results in synergistic effects with docetaxel and cisplatin in PTEN positive or negative prostate cancer models. These results provide a rationale for clinical development with conventional chemotherapy and inhibitors of the PI3K/Akt/mTOR pathway," said Dr. Festuccia.

Additionally, Paloma Pharmaceuticals presented at the American Association for Cancer Research (AACR) Special Conference "Targeting PI3K/mTOR Signaling in Cancer" in San

Francisco, CA entitled, “Palomid 529, an allosteric TORC1/TORC2 inhibitor of the PI3K/Akt/mTOR pathway, shows differential effects compared to TORC1 inhibition”. “Work described here shows that in a variety of model systems, there is advantage of inhibiting both TORC1 and TORC2 over that of TORC1. Other TORC1/TORC2 inhibitors are currently in human Phase I/II studies but differ with P529 in that they are catalytic inhibitors able to inhibit mTOR within the TORC1/TORC2 complexes. Although these inhibitors inhibit one protein found within the TORC2 complexes via competitive inhibition, they would not be expected to dissociate the complexes nor inhibit the activity of the other proteins within the complexes. As P529 causes the dissociation of the complexes, P529 would be expected to have broader activity over that of the mTOR catalytic inhibitors,” said Dr. Sherris.

About Paloma Pharmaceuticals

Paloma Pharmaceuticals, Inc. is a drug development company using PI3K/Akt/mTOR inhibitors for cancer, ocular, CNS, fibrotic, antiviral and skin diseases. Paloma owns intellectual property relating to a library of novel, proprietary, small molecule drugs created through an integrated design platform incorporating proprietary, customized and industry standard computational tools.

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