

Paloma Pharmaceuticals Receives Approval to Enter Phase I Clinical Trials

-- IND Accepted by FDA to Initiate Intravitreal and Subconjunctival Administration of Palomid 529 in Age-Related Macular Degeneration Patients --

Jamaica Plain, MA, 4 February 2010 /PRNewswire/ -- Paloma Pharmaceuticals, Inc. announced today that it has received acceptance of its IND to enter Phase I studies with Palomid 529 (P529) in patients with age-related macular degeneration (AMD). The Phase I study, "A Phase I Open-Label Study to Investigate the Safety, Tolerability and Pharmacokinetic Profile of Single Intravitreal and Subconjunctival Doses of Palomid 529 in Patients with Advanced Neovascular Age-Related Macular Degeneration" will be a dose-ranging study aimed at safety but will also have objective measurement for efficacy.

P529 is a non-steroidal, synthetic, small molecule drug created through computational design, synthetic and medicinal chemistry, the result of three generations of Palomid design work. P529's broad activity resides in its ability to target and inhibit the PI3K/Akt/mTOR signal transduction pathway as a dual TORC1/TORC2 inhibitor. It is a first-in-class PI3K/Akt/mTOR inhibitor causing the dissociation of both the TORC1 and TORC2 complexes.

"As P529 is an inhibitor of both the TORC1 and TORC2 arms ultimately controlling the PI3K/Akt/mTOR pathway it would be expected to have broad activity as an anti-angiogenic agent and further inhibit vascular permeability, two aspects that make a compelling story for clinical studies in AMD. We look forward to working with Paloma Pharmaceuticals on this interesting approach to wet AMD" said Dr. Jeffrey Heier, M.D., principal investigator of the study with Ophthalmic Consultants of Boston.

"We are pleased to have the FDA accept our IND package for initiation of Phase I human studies. This external validation of P529 as a therapeutic agent to combat eye disease gives credence to not just our program for ocular disease but as P529 will be used formulated for other therapeutic areas, it also leads the way for acceptance of up-coming Phase I studies in cancer, epilepsy, dermatologic diseases and other indication areas in our pipeline", said Dr. David Sherris, Ph.D., President and CEO of Paloma Pharmaceuticals.

About the PI3K/Akt/mTOR Pathway and Ocular Diseases of Neovasculation

The PI3K/Akt/mTOR pathway has been implicated in a wide variety of biological responses and is considered a major therapeutic target in an assortment of diseases. Ocular diseases of neovasculation, AMD and diabetic retinopathy (DR), create aberrant retinal vessels by secreting pro-angiogenic factors to induce the angiogenic cascade. Aberrant vessels caused by pathological angiogenesis produce a variety of pathologies including edema and hemorrhage due in part by release of vascular endothelial growth factor (VEGF), inducing angiogenesis and vascular leakage. As the PI3K/Akt/mTOR pathway is activated by a wide variety of pro-angiogenic cytokines, including but not limited to VEGF, agents capable of inhibiting the pathway is an attractive target for therapeutic intervention. Central within the

PI3K/Akt/mTOR signalling pathway are two distinct protein complexes, TORC1 and TORC2. TORC1 antagonists (rapamycin, also called Sirolimus) have shown activity in animal models of AMD and DR, and in human clinical trials. As inhibition of both TORC1 and TORC2 should result in greater control of PI3K/Akt/mTOR signaling, dual inhibitors such as P529 would be expected to exert increased activity in back of the eye diseases of neovasculature.

About Paloma Pharmaceuticals

Paloma Pharmaceuticals, Inc. is a drug development company with PI3K/Akt/mTOR inhibitors for cancer, ocular diseases (AMD and DR), CNS (epilepsy, Parkinson's, Alzheimer's, Huntington's and Schizophrenia), fibrotic diseases (pulmonary and renal fibrosis), antiviral (HIV, HCV) and skin diseases (psoriasis and atopic dermatitis). Paloma owns the 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.

About Ophthalmic Consultants of Boston

Ophthalmic Consultants of Boston (OCB) was founded in 1969 with the primary goal of providing patients with eye care, laser and surgical treatment of the highest quality. In addition to eye examinations, OCB ophthalmologists provide care in the following specialties: cataract, glaucoma, cornea, diseases of the retina, orbital plastics, pediatrics, LASIK refractive surgery and eye trauma. OCB's staff of 26 ophthalmologists cares for over 150,000 patients each year with all categories of eye disorders and visual system diseases. This level of care has earned Ophthalmic Consultants of Boston a national and international reputation for excellence.

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