Pfizer Logo

Lpath Initiates Dosing of iSONEP in First of Two Proof-ofConcept Trials

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PEDigree Trial to Study Effects of iSONEP in Patients With RPE Detachment

Lpath, Inc. (OTCBB: LPTN), the industry leader in lipidomics-based antibody therapeutics, has initiated dosing in its PEDigree clinical trial where iSONEP(TM) is being investigated as a treatment for retinal pigment epithelium detachment ("RPE detachment" or "PED"). Lpath entered into an agreement with Pfizer (NYSE: PFE) in 2010 that provides Pfizer an exclusive option for a worldwide license to develop and commercialize iSONEP.

In this human proof-of-concept trial, Lpath plans to dose 32 subjects -- 16 at a lower dose and 16 at a higher dose -- that have PED secondary to wet age-related macular degeneration (wet AMD) or polypoidal choroidal vasculopathy (PCV).

PED is a potentially serious condition that is often part of the pathology of wet AMD and PCV, yet no drug has yet been approved to treat PED. Even though patients with PED were excluded from the Lucentis(R) pivotal trials, this drug is often used to treat such patients, but with incomplete success. As such, the prognosis for those suffering from PED continues to be poor.

Subjects in the PEDigree trial will receive up to three monthly intravitreal injections of iSONEP. The primary safety endpoint is the tolerability of consecutive monthly injections, and the primary efficacy endpoint is the percentage of subjects that experience complete flattening of their PED.

In Lpath's Phase 1 trial, where subjects with wet AMD received only one injection, iSONEP met its primary endpoint of being well tolerated in all 15 patients. It also succeeded in meeting a key secondary endpoint in that a positive biological effect -- with a single dose -- was observed in most patients, almost all of whom had failed to respond to Lucentis and/or Avastin(R) treatment.

One of the distinct benefits in Phase 1 was the resolution (complete flattening) of PEDs in two out of the two subjects that presented with PED. One of these patients received no further treatment with the "standard of care" (Lucentis or Avastin) during the entire 12-month monitoring period following the iSONEP injection. The other was not re-treated until day 105. These extended times to re-treatment suggest that any benefit derived from iSONEP is durable, a particularly important attribute in this market. Lpath hypothesizes that such distinctive benefits are due to iSONEP's powerful anti-inflammatory and antifibrotic mechanisms of action. In various animal models of disease, iSONEP was shown to substantially reduce inflammation in the eye (Campochiaro et al., Journal of Cellular Physiology, October 2008) and significantly mitigate ocular fibrosis (Grant et al., Experimental Eye Research, August 2008). The potential market for a drug that fully resolves PED is significant: it is estimated more than 500,000 people currently have PED, and with reasonable assumptions, the attainable market size is estimated to be more than $1.0 billion globally. These figures are expected to grow significantly as

the "baby boomers" fill up the ranks of the 65+ age group.

Lpath plans to soon begin another iSONEP trial, a double-blind, 160-subject human-proof-of-concept trial to study the efficacy and safety of iSONEP in the broader wet-AMD patient population. Glenn Stoller, MD, head of Lpath's ocular division, commented: "iSONEP is a first-in-class drug that has distinguished itself with promising animal data and, more recently, human data. A growing independent body of literature suggests that iSONEP's distinctive anti-inflammatory, anti-angiogenic and anti-fibrotic mechanisms could prevent both the early and the late stages of retinal damage, including the damage that often results when a PED fails to flatten over time."

Scott Pancoast, Lpath's president and chief executive officer, added: "Because anti-VEGF agents like Lucentis and Avastin have demonstrated lackluster results in the treatment of PED patients, there is a significant unmet medical need. Both subjects presenting with PED in our Phase 1 trial experienced a complete flattening of the PED. While that is a very small population, we are hopeful that we will see similar results in larger groups of patients as we continue our clinical development program." Lucentis(R) and Avastin(R) are registered trademarks of Roche.

About Lpath

San Diego-based Lpath, a therapeutic antibody company, is the category leader in lipidomics-based antibody therapeutics, an emerging field of medicine that targets bioactive signaling lipids for treating a wide range of human disease. Lpath's ImmuneY2(TM) drug-discovery engine has the unique ability to generate therapeutic antibodies that bind to and inhibit bioactive lipids that contribute to disease. The company has developed three drug candidates, one of which (iSONEP(TM) for wet AMD) has initiated mid-stage clinical trials and another of which (ASONEP(TM) for cancer) will soon begin mid-stage clinical trials. The third candidate is a pre-clinical anti-LPA antibody, which has shown efficacy in animal models of pain, fibrosis, and traumatic brain injury. Lpath entered into an agreement with Pfizer (NYSE: PFE) in 2010 that provides Pfizer an exclusive option for a worldwide license to develop and commercialize iSONEP. For more information, visit www.Lpath.com.

About Forward-Looking Statements

The Company cautions you that the statements included in this press release that are not a description of historical facts are forward-looking statements. These include statements regarding: the eventual commercial viability of the Company's drug programs, and the eventual revenues that the Company would attain if the drug eventually gets approved. Actual results may differ materially from those set forth in this press release due to the risks and uncertainties inherent in the Company's business, including, without limitation: the results of any future clinical trials for iSONEP may not be favorable and the Company may never receive regulatory approval for iSONEP; and the Company may not be able to secure the funds necessary to support its clinical trial and product development plans. More detailed information about the Company and the risk factors that may affect the realization of forward-looking statements is set forth in the Company's filings with the Securities and Exchange Commission, including its Annual Report on Form 10-K and its Quarterly Reports on Form 10-Q filed with the SEC. Such documents may be read free of charge on the SEC's web site at www.sec.gov. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement and the Company undertakes no obligation to revise or update this press release to reflect events or circumstances after the date hereof. This caution is made under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995.

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