Pfizer Logo

Lpath Completes Enrollment in its Phase 2 Clinical Trial of iSONEP for Wet Age-Related Macular Degeneration

Tuesday, December 02, 2014 - 08:00am

Conference Call Scheduled for Wednesday, December 3 to Provide Investor Update

SAN DIEGO, December 2, 2014 – Lpath, Inc. (NASDAQ: LPTN), the industry leader in bioactive lipidtargeted therapeutics, announced that in consultation with Pfizer Inc., Lpath has completed enrollment of its clinical study evaluating iSONEP™ in patients with wet age-related macular degeneration (wet AMD), which is also referred to as the "Nexus" study. This multicenter, Phase 2 clinical trial enrolled patients who have not responded well to existing anti-vascular endothelial growth factor (VEGF) therapies including Lucentis®, Avastin® and Eylea®.

Top line study results are expected to be available in the second quarter of 2015. The Nexus Data Safety Monitoring Board (DSMB) continues to express no significant safety concerns with the study treatments and has encouraged Lpath to close enrollment by the end of the year.

"We are eager to advance our lead program to data analysis in order to evaluate proof-of-concept of iSONEP in patients with wet AMD, either as an adjunctive or monotherapy," stated Dario Paggiarino, M.D., senior vice president and chief development officer of Lpath. "Lpath expects that the results from the Nexus study will provide additional insights as to whether or not iSONEP has biologic activity in the multiple mechanisms that underlie wet AMD-related vision loss, in addition to vascular leakage."

The primary endpoint of the Nexus study is a mean change in best corrected visual acuity (BCVA) at 120 days. Secondary endpoints include measurements of retinal thickness, neovascular lesion size and safety, among others. iSONEP is an antibody that blocks the bioactive lipid sphingosine-1-phosphate (S1P), implicated in choroidal neovascularization, inflammation and fibrosis – all of which are believed to be important factors in the development of wet AMD.

Lpath is also conducting a Phase 2a trial evaluating ASONEP™, an anti-S1P antibody that is formulated for systemic delivery, in patients with metastatic renal cell carcinoma. Lpath has also utilized its ImmuneY2™ drug discovery engine to produce LpathomabTM (an antibody targeting lysophosphatidic acid, or LPA), for which investigational new drug (IND) enabling studies have been completed. In addition, Lpath is planning to file an IND application with the United States Food and Drug Administration for Lpathomab for the treatment of neuropathic pain in January 2015. The company plans to initiate a Phase 1 safety study of Lpathomab in the first quarter of 2015.

Investor Update Conference Call Tomorrow
Lpath will host a webcast and conference call tomorrow, Wednesday, December 3, 2014 beginning at 8:30 a.m. Eastern Standard Time/5:30 a.m. Pacific Standard Time to update investors on the progress of the Nexus trial as well as Lpath's other clinical and preclinical programs. To listen to the live webcast please visit the "Investor Calendar of Events" section of Lpath's corporate website at www.Lpath.com. A webcast replay will be available

shortly after the call at the same web address. To participate by telephone, please dial # (domestic callers) or # (international callers). A telephone replay will be available afterward by dialing # (domestic callers) or # (international callers) using conference ID number #.

About Lpath

San Diego-based Lpath, Inc. (NASDAQ: LPTN) is the category leader in lipid-targeted therapeutics. The company's ImmuneY2™ 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 four drug candidates, two of which—iSONEP for wet AMD and ASONEP for cancer—are currently being investigated in Phase 2 trials. The other candidates are an anti-LPA antibody, Lpathomab, for neuropathic pain and an anti-leukotriene antibody, Altepan, which is being studied in models of inflammatory bowel disease, respiratory disease and inflammation. For more information, visit www.Lpath.com.

Forward-Looking Statements

Lpath cautions you that the statements included in this press release that are not a description of historical facts are forward-looking statements. Actual results may differ materially from those set forth in this press release due to the risks and uncertainties inherent in Lpath's business, including, without limitation: the final results of Lpath's preclinical studies and clinical trials may be different from interim data results and may not support further clinical development and/or the commercialization of its drug candidates; Lpath may not successfully complete its existing and any additional clinical trials for its drug candidates on a timely basis, or at all; Lpath may fail to obtain required governmental approvals for any of its drug candidates; Lpath may not be successful in maintaining its commercial relationship with Pfizer Inc. or any third party that may acquire the exclusive option we granted to Pfizerfor iSONEP; and Lpath may not be able to secure the funds necessary to support its preclinical-development and clinical-development plans. More detailed information about the risk factors and uncertainties that may affect the realization of forward-looking statements is set forth in Lpath's filings with the Securities and Exchange Commission (the "SEC"), including its Annual Report on Form 10-K, its Quarterly Reports on Form 10-Q, and its other filings with the SEC. Such documents may be read free of charge on the SEC's website at www.sec.gov. You are cautioned not to place undue reliance on these forwardlooking statements, which are effective only as of the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement, and Lpath 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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