Pfenex And Hospira Announce Collaboration To Develop And Commercialize Proposed LUCENTIS® Biosimilar

SAN DIEGO and LAKE FOREST, Ill., Feb. 10, 2015 /PRNewswire/ -- Pfenex Inc. (NYSE MKT: PFNX), a clinical-stage biotechnology company engaged in the development of biosimilar therapeutics, and Hospira, Inc., (NYSE: HSP), the world's leading provider of injectable drugs and infusion technologies, and a global leader in biosimilars, today announced that the companies have entered into an agreement to exclusively develop and commercialize for worldwide sales PF582, Pfenex's biosimilar candidate to Genentech's **LUCENTIS**® (ranibizumab injection). LUCENTIS had estimated global sales of approximately $4 billion in 2014 and is part of the broader $6.7 billion intraocular anti-VEGF (vascular endothelial growth factor) therapeutic segment.

Under the terms of the collaboration, Pfenex will receive an upfront payment of $51 million once the collaboration receives antitrust approval, and, over the next five years and beyond, will be eligible to receive a combination of development and sales-based milestone payments up to an additional $291 million, and tiered double-digit royalty on net sales of the product.

Pfenex and Hospira will share the Phase 3 equivalence clinical trial costs, and Hospira will be responsible for manufacturing and commercializing the product worldwide. The collaboration will be governed by an Executive Steering Committee consisting of equal representation from Pfenex and Hospira. The agreement also allows for additional future product collaborations.

"We are extremely pleased to announce our collaboration with Hospira, a recognized world leader in biosimilars. This collaboration further validates the product development strength and capability of Pfenex as we continue to advance our pipeline of biosimilar candidates," said Bertrand Liang, chief executive officer, Pfenex Inc.

Pfenex is currently conducting a Phase 1b/2a clinical trial where 24 patients have been randomized to receive monthly intraocular injections of PF582 or LUCENTIS for 3 doses and ongoing patient follow-up for 12 months. The clinical trial's primary objective is to evaluate safety and tolerability of PF582, with secondary objectives including comparative pharmacokinetic (PK) and pharmacodynamic (PD) evaluations to help demonstrate biosimilarity to LUCENTIS.

"We are excited to be entering this collaboration with Pfenex for its biosimilar candidate to LUCENTIS, which we expect will expand Hospira's biosimilars pipeline to include a new therapeutic area. Pfenex has established expertise in the development of biosimilars, leveraging its proprietary expression technology together with differentiated bioanalytical characterization capabilities," said Sumant Ramachandra, M.D., Ph.D., senior vice president, chief scientific officer, Hospira. "We look forward to working closely with the Pfenex team to offer patients, physicians and healthcare systems a more affordable treatment option for retinal diseases."

The agreement is subject to review under the Hart-Scott-Rodino Antitrust Improvements Act.

About Pfenex Inc.
Pfenex Inc. is a clinical-stage biotechnology company engaged in the development of biosimilar therapeutics and high-value and difficult to manufacture proteins. The company's lead product candidate is PF582, a biosimilar candidate to LUCENTIS (ranibizumab), for the potential treatment of patients with retinal diseases. Pfenex has leveraged its *Pfe*nex Expression Technology® platform to build a pipeline of product candidates and preclinical products under development including other biosimilars, as well as vaccines, generics and next generation biologics.

Pfenex has used, and intends to continue to use, its Investor Relations website (http://pfenex.investorroom.com), as means of disclosing material non-public information and for complying with its disclosure obligations under Regulation FD. For more information, visit (http://pfenex.investorroom.com).

About Hospira
Hospira, Inc. is the world's leading provider of injectable drugs and infusion technologies, and a global leader in biosimilars. Through its broad, integrated portfolio, Hospira is uniquely positioned to Advance Wellness™ by improving patient and caregiver safety while reducing healthcare costs. The company is headquartered in Lake Forest, Ill. Learn more at www.hospira.com .

Private Securities Litigation Reform Act of 1995 --
A Caution Concerning Forward-Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Forward-looking statements generally relate to future events or Pfenex's or Hospira's future financial or operating performance. In some cases, you can identify forward-looking statements because they contain words such as "may," "will," "should," "expects," "plans," "anticipates," "could," "intends," "target," "projects," "contemplates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of these words or other similar terms or expressions that concern either of Pfenex's or Hospira's expectations, strategy, plans or intentions. Forward-looking statements in this press release include, but are not limited to: in the case of Pfenex, statements regarding the future potential of PF582, including future plans to develop, manufacture and commercialize PF582 and the potential to receive future milestone and royalty payments; and in the case of Hospira, its expectations regarding regulatory approvals, clinical trials and the actions of competitors. The companies' expectations and beliefs regarding these matters may not materialize, and actual results in future periods are subject to risks and uncertainties that could cause actual results to differ materially from those projected. Actual results may differ materially from those indicated by these forward-looking statements as a result of various important factors, including, without limitation, challenges inherent in creating and developing compounds and product candidates and economic, competitive, governmental, regulatory, legal, supply and other factors. Information on these and additional risks affecting Hospira's business and operating results are more fully discussed in the section entitled "Risk Factors" in its most recently filed annual report on Form 10-K, as updated by any subsequently filed quarterly report on Form 10-Q. Information on these and additional risks affecting Pfenex's business and operating results are more fully discussed in the section entitled "Risk Factors" in its most recently filed quarterly report on Form 10-Q for the quarter ended September 30, 2014 and Pfenex's subsequent periodic reports, including Pfenex's Form 10-K for the year ended December 31, 2014, which is expected to be filed with the SEC in March of 2015. The forward-looking statements in this press release are based on information available as of the date hereof, and each of Pfenex and Hospira disclaims any obligation to update any forward-looking statements, except as required by law.

To view the original version on PR Newswire, visit: http://www.prnewswire.com/news-releases/pfenex-and-hospira-announce-collaboration-to-develop-and-commercialize-proposed-lucentis-biosimilar-300033296.html

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