

# Jazz Pharmaceuticals and Pfenex Enter into a Worldwide License and Option Agreement Related to Product Candidates in Early Development for Hematological Malignancies

July 28, 2016

DUBLIN and SAN DIEGO, July 28, 2016 /PRNewswire/ -- Jazz Pharmaceuticals plc (Nasdaq: JAZZ) and Pfenex Inc. (NYSE MKT: PFNX) today announced an agreement under which Pfenex granted Jazz Pharmaceuticals worldwide rights to develop and commercialize multiple early stage hematology product candidates. The agreement also includes an option for Jazz Pharmaceuticals to negotiate a license for a recombinant pegaspargase product candidate with Pfenex. This early development stage collaboration demonstrates Jazz Pharmaceuticals' focus on identifying innovative technologies that may lead to the development of important therapeutic options for patients with hematological malignancies.

Under the agreement, Pfenex will receive upfront and option payments totaling \$15 million and may be eligible to receive additional payments of up to \$166 million based on the achievement of certain development-, regulatory-, and sales-related milestones, including up to \$41 million for certain non-sales-related milestones. Pfenex may also be eligible to receive tiered royalties on worldwide sales of any products resulting from the collaboration. Both parties will be contributing to development efforts.

"The collaboration with Pfenex, including access to its unique protein expression technology, demonstrates our emphasis on diversifying and strengthening our portfolio to provide improved therapeutic options for patients." said Karen Smith M.D., Ph.D, global head of research and development and chief medical officer at Jazz Pharmaceuticals plc. "We look forward to working with Pfenex on the development of multiple product candidates that have the potential to broaden our hematology/oncology portfolio."

"Our collaboration with Jazz further validates Pfenex's product development capability enabled by our protein expression platform technology. We look forward to working with Jazz on these assets in support of further advancement in clinical development," said Bertrand C. Liang, chief executive officer of Pfenex.

#### **About Pfenex Inc.**

Pfenex Inc. (NYSE MKT: PFNX) 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 *Pf*enex Expression Technology<sup>®</sup> platform to build a pipeline of product candidates and preclinical products under development including other biosimilars, as well as vaccines, therapeutic equivalents to reference listed drug products, and next generation biologics. For more information, please visit <a href="https://www.pfenex.com">www.pfenex.com</a>.

## **About Jazz Pharmaceuticals**

Jazz Pharmaceuticals plc (Nasdaq: JAZZ) is an international biopharmaceutical company focused on improving patients' lives by identifying, developing and commercializing meaningful products that address unmet medical needs. The company has a diverse portfolio of products and product candidates, with a focus in the areas of sleep and hematology/oncology. In these areas, Jazz Pharmaceuticals markets Xyrem® (sodium oxybate) oral solution, Erwinaze® (asparaginase *Erwinia chrysanthemi*) and Defitelio® (defibrotide sodium) in the U.S. and markets Erwinase® and Defitelio® (defibrotide) in countries outside the U.S. For more information, please visit <a href="www.jazzpharmaceuticals.com">www.jazzpharmaceuticals.com</a>.

### Jazz Pharmaceuticals' "Safe Harbor" Statement under the Private Securities Litigation Reform Act of 1995

This press release contains forward-looking statements, including, but not limited to, statements related to the potential benefits of certain preclinical product candidates and related development activities, potential future payments to Pfenex by Jazz Pharmaceuticals, the potential broadening of Jazz Pharmaceuticals' product portfolio and other statements that are not historical facts. These forward-looking statements are based on Jazz Pharmaceuticals' current plans, objectives, estimates, expectations and intentions, and inherently involve significant risks and uncertainties. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, risks and uncertainties associated with the difficulty and uncertainty of pharmaceutical product development and the uncertainty of preclinical and clinical success, and the risks and uncertainties described from time to time under the caption "Risk Factors" and elsewhere in Jazz Pharmaceuticals plc's Securities and Exchange Commission filings and reports (Commission File No. 001-33500), including the company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2016 and future filings and reports by the company. Other risks and uncertainties of which Jazz Pharmaceuticals is not currently aware may also affect its forward-looking statements and may cause actual results and timing of events to differ materially from those anticipated. The forward-looking statements herein are made only as of the date hereof or as of the dates indicated in the forward-looking statements, even if they are subsequently made available by Jazz Pharmaceuticals on its website or otherwise. Jazz Pharmaceuticals does not undertake any obligation to update or supplement any forward-looking statements to reflect actual results, new information, future events, changes in expectations or other circumstances that exist after the date as of which the forward-l

# <u>Pfenex Cautionary Note Regarding Forward-Looking Statements</u>

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements generally relate to future events or Pfenex's future financial or operating performance. In some cases, forward-looking statements can be identified 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 Pfenex's expectations, strategy, plans or intentions. Forward-looking statements in this press release include, but are not limited to, statements regarding the future potential of the hematology product candidates, including future plans to develop, manufacture and commercialize these product candidates; the potential to receive future milestone and royalty payments under Pfenex's agreements with Jazz Pharmaceuticals; and the belief that these product candidates may lead to therapeutic options for patients with hematological malignancies. Actual results may differ materially from those indicated by these forward-looking statements as a result of the uncertainties inherent in the clinical drug development process, including, without limitation, challenges in successfully demonstrating the efficacy and safety of product candidates; the pre-clinical and clinical results

for product candidates, which may not support further development of product candidates or may require additional clinical trials or modifications of ongoing clinical trials or regulatory pathways; challenges related to commencement, patient enrollment, completion, and analysis of clinical trials; Pfenex's ability to obtain additional funding to support its business activities and establish and maintain strategic business alliances and new business initiatives; Pfenex's dependence on third parties for development, manufacture, marketing, sales and distribution of products; unexpected expenditures; and difficulties in obtaining and maintaining intellectual property protection for product candidates. Information on these and additional risks, uncertainties, and other information affecting Pfenex's business and operating results is contained in Pfenex's Annual Report on Form 10-K for the year ended December 31, 2015, Pfenex's Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, and in Pfenex's subsequent reports filed with the Securities and Exchange Commission. The forward-looking statements in this press release are based on information available to Pfenex as of the date hereof, and Pfenex disclaims any obligation to update any forward-looking statements, except as required by law.

Pfenex investors and others should note that Pfenex announces material information to the public about Pfenex through a variety of means, including its website (<a href="http://www.pfenex.com/">http://www.pfenex.com/</a>), investor relations website (<a href="http://pfenex.investorroom.com/">http://pfenex.investorroom.com/</a>), press releases, SEC filings, public conference calls, corporate Twitter account (<a href="https://www.facebook.com/Pfenex-Inc-105908276167776/timeline/">https://www.facebook.com/Pfenex-Inc-105908276167776/timeline/</a>), and LinkedIn page (<a href="https://www.linkedin.com/company/pfenex-inc">https://www.linkedin.com/company/pfenex-inc</a>) in order to achieve broad, non-exclusionary distribution of information to the public and to comply with its disclosure obligations under Regulation FD. Pfenex encourages its investors and others to monitor and review the information Pfenex makes public in these locations as such information could be deemed to be material information. Please note that this list may be updated from time to time.



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To view the original version on PR Newswire, visit: <a href="http://www.prnewswire.com/news-releases/jazz-pharmaceuticals-and-pfenex-enter-into-a-worldwide-license-and-option-agreement-related-to-product-candidates-in-early-development-for-hematological-malignancies-300305816.html">http://www.prnewswire.com/news-releases/jazz-pharmaceuticals-and-pfenex-enter-into-a-worldwide-license-and-option-agreement-related-to-product-candidates-in-early-development-for-hematological-malignancies-300305816.html</a>

SOURCE Jazz Pharmaceuticals plc

Jazz Pharmaceuticals Contacts: Investors: Kathee Littrell, Vice President, Investor Relations, Ireland, +353 1 634 7887, U.S., +1 650 496 2717; Media: Laurie Hurley, Vice President, Corporate Affairs, Ireland, +353 1 634 7894, U.S., +1 650 496 2796; Pfenex Contact: Paul Wagner, Ph.D., Chief Financial Officer, (858) 352-4333, pwagner@pfenex.com