Jazz Pharmaceuticals and Codiak BioSciences Announce Strategic Collaboration to Research, Develop and Commercialize Engineered Exosomes to Create Therapies for Hard-to-Treat Cancers

January 3, 2019

- Collaboration strengthens Jazz portfolio with novel therapeutic approach that has potential to provide transformational benefit to subgroup of patients with modulations in well validated but previously undruggable targets
- Codiak to receive \$56 million upfront, up to \$200 million in milestones for each of five targets, additional preclinical development milestones of up to \$20 million, a co-commercialization option on two products, and royalties on future net sales
 - Jazz conference call to be held tomorrow, January 4, 2019, at 8:30 a.m. EST / 1:30 p.m. GMT

DUBLIN and CAMBRIDGE, Mass., Jan. 3, 2019 /PRNewswire/ -- Jazz Pharmaceuticals plc (Nasdaq: JAZZ) and Codiak BioSciences, Inc. today announced that the companies have entered into a strategic collaboration agreement focused on the research, development and commercialization of exosome therapeutics to treat cancer. Codiak granted Jazz an exclusive, worldwide, royalty-bearing license to develop, manufacture and commercialize therapeutic candidates directed at five targets to be developed using Codiak's engEx[™] precision engineering platform for exosome therapeutics. The targets focus on oncogenes that have been well validated in hematological malignancies and solid tumors but have been undruggable with current modalities, including NRAS and STAT3.

Under the terms of the agreement, Codiak is responsible for the execution of pre-clinical and early clinical development of therapeutic candidates directed at all five targets through Phase 1/2 proof of concept studies. Following the conclusion of the applicable Phase 1/2 study, Jazz will be responsible for future development, potential regulatory submissions and commercialization for each product. Codiak has the option to participate in co-commercialization and cost/profit-sharing in the U.S. and Canada on up to two products.

As part of the agreement, Jazz will pay Codiak an upfront payment of \$56 million. Codiak is eligible to receive up to \$20 million in preclinical development milestone payments across all five programs. Codiak is also eligible to receive milestone payments totaling up to \$200 million per target based on Investigational New Drug application acceptance, clinical and regulatory milestones, including approvals in the U.S., European Union and Japan, and sales milestones. Codiak is also eligible to receive tiered royalties on net sales of each approved product, with percentages ranging from mid-single digits in the lowest tier to high teens in the highest tier.

"We are looking forward to partnering with Codiak and their world-class management and R&D team. Their innovative exosome platform offers the opportunity to address targets that have been frequently implicated in hematological malignancies and solid tumors, including targets recognized as undruggable with current approaches," said Bruce Cozadd, chairman and chief executive officer of Jazz Pharmaceuticals. "The exosome approach is differentiated and represents the ideal complement to our CombiPlex® platform and other collaboration programs. The ability to develop multiple new therapies through these technologies is an important advance as we seek to add long-term value for patients and shareholders."

"We are excited to be working with the team at Jazz to bring a new class of medicines into clinical testing to treat patients with cancer," said Douglas E. Williams, PhD, president and chief executive officer of Codiak. "We believe that the Codiak engExTM platform, along with Jazz's insights into relevant but intractable targets, creates a unique opportunity to improve patient outcomes in various cancers. Codiak's proprietary engExTM platform allows us to deliver potent therapeutics in a precise, targeted and tunable way. This collaboration allows Codiak to accelerate the potential of our engExTM platform as we advance our lead candidates and core pipeline."

Exosomes are naturally occurring, nanometer-sized vesicles that are released and received by nearly all cells in the body. They serve as an efficient system of intercellular communication. In the tumor microenvironment, exosomes have been shown to carry molecular messages between tumor and immune cells. Codiak has co-opted this process and, through its engExTM platform, engineers potent drug molecules into the exosome to create bespoke therapeutic candidates which have shown potent preclinical antitumor activity.

With the engExTM platform, Codiak has the ability to incorporate a range of therapeutic drug classes—including small molecules, proteins, peptides, cytokines and nucleic acids—onto the surface or in the lumen of its therapeutic exosomes. engExTM also enables precise modifications of the engineered exosomes to optimize potency and to alter or enhance tropism for directed delivery to desired cell types. These flexible design features allow Codiak to create an optimized exosome therapeutic for the drug target and desired site of action.

Jazz Pharmaceuticals Conference Call Details

Jazz Pharmaceuticals and Codiak will host an investor conference call and live audio webcast on Friday, January 4, 2019 at 8:30 a.m. EST (1:30 p.m. GMT) to discuss the collaboration. The live webcast may be accessed from the Investors section of Jazz Pharmaceuticals' website at www.jazzpharmaceuticals.com. Please connect to the website prior to the start of the conference call to ensure adequate time for any software downloads that may be necessary. Investors may participate in the conference call by dialing +1 855 353 7924 in the U.S., or +1 503 343 6056 outside the U.S., and entering passcode 9698918.

A replay of the conference call will be available through January 11, 2019 by dialing +1 855 859 2056 in the U.S., or +1 404 537 3406 outside the U.S., and entering passcode 9698918. An archived version of the webcast will be available for at least one week in the Investors section of Jazz Pharmaceuticals' website at www.jazzpharmaceuticals.com

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 therapeutic areas, Jazz Pharmaceuticals markets Xyrem[®] (sodium oxybate) oral solution, Erwinaze[®] (asparaginase *Erwinia chrysanthemi*), Defitelio[®] (defibrotide sodium) and Vyxeos[®] (daunorubicin and cytarabine) liposome for injection in the U.S. and markets Erwinase[®], Defitelio[®] (defibrotide) and Vyxeos[®] 44 mg/100 mg powder for concentrate

for solution for infusion in countries outside the U.S. For more information, please visit https://www.jazzpharmaceuticals.com/ and follow us on Twitter at @JazzPharma.

About Codiak BioSciences

Codiak BioSciences is the leader in the emerging field of exosome therapeutics. Founded in 2015 and headquartered in Cambridge, Mass., Codiak has built a proprietary technology platform for exosome engineering and manufacturing that allows for precise therapeutic targeting -- opening the door to the development of therapies to treat a diverse array of diseases that are currently difficult or impossible to treat using existing methodologies. For more information, visit http://www.codiakbio.com.

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 future development of exosome therapeutics to treat cancer; potential clinical, regulatory and sales milestones with respect to certain targets covered by Jazz Pharmaceuticals' strategic collaboration agreement with Codiak; potential future payments by Jazz Pharmaceuticals to Codiak; the potential ability to develop multiple new therapies as Jazz Pharmaceuticals seeks to add long-term value for patients and shareholders; the potential opportunity to improve patient outcomes in various cancers; 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: Jazz Pharmaceuticals' ability to achieve the expected benefits (commercial or otherwise) from the collaboration agreement; pharmaceutical product development and clinical success thereof: the regulatory approval process; and effectively commercializing any product candidates; and other risks and uncertainties affecting Jazz Pharmaceuticals, including those 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 September 30, 2018 and future filings and reports by the company. Other risks and uncertainties of which Jazz Pharmaceuticals is not currently aware may also affect the company's forward-looking statements and may cause actual results and the 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 undertakes no obligation to update or supplement any forward-looking statements to reflect actual results, new information, future events, changes in its expectations or other circumstances that exist after the date as of which the forward-looking statements were made.



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SOURCE Jazz Pharmaceuticals plc

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