Jazz Pharmaceuticals and MD Anderson Cancer Center Collaborate to Evaluate Potential Treatment Options for Hematologic Malignancies

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DUBLIN and HOUSTON, Aug. 6, 2018 /PRNewswire/ -- Jazz Pharmaceuticals plc (Nasdaq: JAZZ) and The University of Texas MD Anderson Cancer Center today announced a five-year collaboration agreement with a goal of evaluating therapies for multiple hematologic malignancies, including acute myeloid leukemia (AML) and myelodysplastic syndromes.

The joint effort brings together MD Anderson's translational medicine and clinical research capabilities with Jazz's hematology/oncology portfolio, including its FDA-approved medicines as well as current and potential future investigational therapies.

"This collaboration represents a significant opportunity to efficiently develop innovative therapies and therapeutic combinations," said Tapan Kadia, M.D., associate professor of Leukemia at MD Anderson. "Our aim is to always provide leading-edge care for our leukemia patients, and it is our hope that this joint effort will result in new treatment solutions."

Jazz and MD Anderson will pursue research opportunities in areas of high unmet need. The initial focus of the collaboration is to evaluate and generate additional data for Vyxeos® (daunorubicin and cytarabine) liposome for injection, in new patient populations and in combination with other therapies.

"Jazz is committed to providing meaningful medicines for people with hematologic cancers, particularly those with serious unmet clinical needs," said Allen Yang, M.D., Ph.D., vice president and acting chief medical officer of Jazz Pharmaceuticals. "We look forward to collaborating with MD Anderson to help advance treatment options for patients as part of our growing hematology oncology therapeutic area."

Vyxeos received FDA approval in August 2017 for the treatment of adults with newly-diagnosed therapy-related (t-AML) or AML with myelodysplasia-related changes (AML-MRC), which represents part of high-risk or secondary AML populations. AML-MRC is more common in older patients who often do not respond well to intensive chemotherapy; while t-AML can occur as a result of previous chemotherapy or radiation therapy.

About Vyxeos
Vyxeos is a liposome formulation of a fixed combination of daunorubicin and cytarabine for intravenous infusion. Vyxeos is indicated for the treatment of adults with newly-diagnosed t-AML or AML-MRC. For more information about Vyxeos in the United States, please visit https://vyxeos.com.

Important Safety Information
Vyxeos has different dosage recommendations from other medications that contain daunorubicin and/or cytarabine. Do not substitute Vyxeos for other daunorubicin- and/or cytarabine- containing products.

Vyxeos should not be given to patients who have a history of serious allergic reaction to daunorubicin, cytarabine or any of its ingredients.

Vyxeos can cause a severe decrease in blood cells (red and white blood cells and cells that prevent bleeding, called platelets) which can result in serious infection or bleeding and possibly lead to death. Your doctor will monitor your blood counts during treatment with Vyxeos. Patients should tell the doctor about new onset fever or symptoms of infection or if they notice signs of bruising or bleeding.

Vyxeos can cause heart-related side effects. Tell your doctor about any history of heart disease, radiation to the chest, or previous chemotherapy. Inform your doctor if you develop symptoms of heart failure such as:

- shortness of breath or trouble breathing
- swelling or fluid retention, especially in the feet, ankles or legs
- unusual tiredness

Vyxeos may cause allergic reactions including anaphylaxis. Seek immediate medical attention if you develop signs and symptoms of anaphylaxis such as:

- trouble breathing
- severe itching
- skin rash or hives
- swelling of the face, lips, mouth, or tongue

Vyxeos contains copper and may cause copper overload in patients with Wilson's disease or other copper-processing disorders.

Vyxeos can damage the skin if it leaks out of the vein. Tell your doctor right away if you experience symptoms of burning, stinging, or blisters and skin sores at the injection site. Vyxeos can harm your unborn baby. Inform your doctor if you are pregnant, planning to become pregnant, or nursing. Do not breastfeed while receiving Vyxeos. Females and males of reproductive potential should use effective contraception during treatment and for 6 months following the last dose of Vyxeos.

The most common side effects were bleeding events, fever, rash, swelling, nausea, sores in the mouth or throat, diarrhea, constipation, muscle pain, tiredness, stomach pain, difficulty breathing, headache, cough, decreased appetite, irregular heartbeat, pneumonia, blood infection, chills, sleep disorders, and vomiting.

Please see full Prescribing Information for Vyxeos including BOXED Warning at http://pp.jazzpharma.com/pi/vyxeos.en.USPI.pdf

About MD Anderson Cancer Center
The University of Texas MD Anderson Cancer Center in Houston ranks as one of the world's most respected centers focused on cancer patient care, research, education and prevention. The institution's sole mission is to end cancer for patients and their families around the world. MD Anderson is one of only 49 comprehensive cancer centers designated by the National Cancer Institute (NCI). MD Anderson is ranked No.1 for cancer care in U.S. News & World Report's "Best Hospitals" survey. It has ranked as one of the nation's top two hospitals for cancer care since the survey began in 1990, and has ranked first 13 times in the last 16 years. MD Anderson receives a cancer center support grant from the NCI of the National Institutes of Health (P30 CA016672).

About Jazz Pharmaceuticals plc
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*), Defitelio® (defibrotide sodium) and Vyxeos® (daunorubicin and cytarabine) liposome for injection in the U.S. and markets Erwinase® and Defitelio® (defibrotide) in countries outside the U.S. For country-specific product information, please visit www.jazzpharmaceuticals.com/products. For more information, please visit www.jazzpharmaceuticals.com and follow us on Twitter at @JazzPharma.

"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 collaboration between Jazz Pharmaceuticals and MD Anderson, including the goal of evaluating and developing potential new treatment options for multiple hematologic malignancies, 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: pharmaceutical product development and clinical success thereof; the regulatory approval process; effectively commercializing Jazz Pharmaceuticals' products and product candidates; and other risks and uncertainties affecting Jazz Pharmaceuticals and its development programs, 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 March 31, 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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