National Comprehensive Cancer Network® adds Jazz Pharmaceuticals' Vyxeos™ (daunorubicin and cytarabine) Liposome for Injection to Clinical Practice Guidelines in Oncology

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DUBLIN, Feb. 8, 2018 /PRNewswire/ -- Jazz Pharmaceuticals plc (Nasdaq: JAZZ) today announced that the National Comprehensive Cancer Network® (NCCN®) added Vyxeos™ (daunorubicin and cytarabine) liposome for injection to the Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Acute Myeloid Leukemia (AML).

The United States Food and Drug Administration (FDA) approved *Vyxeos* on August 3, 2017 for the treatment of adults with two types of AML, a rapidly progressing and life-threatening blood cancer. *Vyxeos* is the first FDA-approved treatment specifically for adults with newly-diagnosed Therapy-Related AML (t-AML) or AML with Myelodysplasia-Related Changes (AML-MRC). Based on the data from the pivotal Phase 3 randomized trial of *Vyxeos* versus the standard of care, the NCCN Guidelines now include a Category 1 recommendation for use of *Vyxeos* for adult patients 60 years of age or greater with newly-diagnosed t-AML or AML-MRC. The Category 1 recommendation indicates that based upon high-level evidence, there is uniform NCCN consensus that *Vyxeos* is appropriate for these patients.

"We appreciate the decision by the NCCN to incorporate *Vyxeos* into the Clinical Practice Guidelines in Oncology as it supports our commitment to ensuring that patients, through their health care professionals, are able to access this important new treatment option," said Karen Smith, M.D., Ph.D., executive vice president of research and development and chief medical officer of Jazz Pharmaceuticals. "*Vyxeos* is the first chemotherapy advance for adults with newly-diagnosed t-AML or AML-MRC in more than 40 years."

The NCCN, a not-for-profit alliance of 27 leading U.S. cancer centers devoted to patient care, research, and education, is dedicated to improving the quality, effectiveness, and efficiency of cancer care. The intent of the NCCN Guidelines is to assist in the decision-making process of individuals involved in cancer care—including physicians, nurses, pharmacists, payers, patients and their families—with the ultimate goal of improving patient care and outcomes.

About Vyxeos™

Vyxeos™ (daunorubicin and cytarabine) liposome for injection 44mg/100mg is a liposome formulation of a fixed combination of daunorubicin and cytarabine for intravenous infusion.[1] *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 before prescribing: http://pp.jazzpharma.com/pi/vyxeos.en.USPI.pdf

About AML

Acute myeloid leukemia (AML) is a blood cancer that begins in the bone marrow, which produces most of the body's new blood cells.[2] AML cells crowd out healthy cells and move aggressively into the bloodstream to spread cancer to other parts of the body.[3] AML is a relatively rare disease representing 1.3 percent of all new cancer cases.[4] It is estimated that more than 21,000 people will be diagnosed with AML in the United States this year with the potential for nearly 11,000 people to die from the disease.[5] The median age at diagnosis is 68 years old,[4] with rising age associated with a progressively worsening prognosis.[6] There is also a reduced tolerance for intensive chemotherapy as patients age.[7] AML has the lowest survival rate of any other form of leukemia.[4] Patients with newly diagnosed t-AML or AML-MRC may have a particularly poor prognosis.[8-10] A hematopoietic stem cell transplant (HSCT) may be a curative treatment option for patients.[11]

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 Erwinaze® 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 addition of Vyxeos to the NCCN Guidelines, Jazz Pharmaceuticals' commitment to ensuring that patients are able to access Vyxeos, and other statements that are not historical facts. These forward-looking statements are based on the company's 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: whether the addition of Vyxeos to the NCCN Guidelines will improve access to Vyxeos by patients covered by the NCCN Guidelines; the company's ability to effectively commercialize Vyxeos in the U.S.; and delays or problems in the supply or manufacture of Vyxeos; and other risks and uncertainties affecting the company, 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, 2017 and future filings and reports by the company. Other risks and uncertainties of which the company is not currently aware may also affect the company's 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 the company on its website or otherwise. The company 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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