



Jazz Pharmaceuticals Secures Eight Additional Provincial Reimbursements for Vyxeos® for Treatment of Adults with Newly Diagnosed Therapy-Related Acute Myeloid Leukemia or Acute Myeloid Leukemia with Myelodysplasia-Related Changes

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MISSISSAUGA, ON, March 8, 2023 /CNW/ - Jazz Pharmaceuticals plc (NASDAQ: JAZZ) announced today that Vyxeos® (daunorubicin and cytarabine liposome for injection) is now included on eight additional provincial drug formularies, including British Columbia, Ontario, Saskatchewan, Manitoba, New Brunswick, Nova Scotia, Alberta, and Newfoundland and Labrador. Vyxeos is indicated for the treatment of adults with newly diagnosed therapy-related acute myeloid leukemia (t-AML) or acute myeloid leukemia (AML) with myelodysplasia-related changes (AML-MRC).¹



In addition to the eight new listings, Vyxeos is also publicly reimbursed in Quebec bringing the total to nine provinces, providing the majority of Canadians access to the important treatment option.

"Because AML is a rapidly progressive cancer and many patients are not candidates for standard therapy, access to new therapies is critical," said Dr. Brian Leber, clinical hematologist, McMaster University Health Centre, Hamilton, Ontario. "Expanding reimbursement of Vyxeos across these provinces is an important milestone for eligible patients as they now have access to a treatment option that may improve their survival."

AML, a cancer of the bone marrow and the blood, progresses rapidly without treatment. Patients diagnosed with t-AML or AML-MRC have a very poor prognosis and have the lowest survival rates of all the AML subgroups.^{2,3} Considered a rare disease, AML affects approximately 1,100 Canadians annually.⁴

"We are pleased with the additional reimbursement decisions that will now allow the majority of patients across the country access to Vyxeos, which was discovered and developed right here in Canada," said Paul Petrelli, general manager of Jazz Pharmaceuticals Canada Inc. "Ensuring reimbursement pathways to life-changing medications for people with rare or complex hematologic disease, like AML, is indicative of Jazz's ongoing commitment to Canadian patients and their families."

The approval of Vyxeos is based on results from a Phase 3 study of 309 adult patients, aged 60-75, with newly diagnosed t-AML or AML-MRC. The study met its primary endpoint as Vyxeos demonstrated a superior improvement in overall survival compared to the current conventional treatment group. The median overall survival for the Vyxeos treatment group was 9.6 months compared with 6 months for the current conventional treatment group.¹

Vyxeos received Health Canada approval for the treatment of t-AML and AML-MRC in April 2021.

About Vyxeos¹

Vyxeos (daunorubicin and cytarabine liposome for injection) is a chemotherapy treatment option specifically indicated for the treatment of adults with newly diagnosed therapy-related acute myeloid leukemia (t-AML) or AML with myelodysplasia-related changes (AML-MRC). Vyxeos is administered by intravenous infusion over a period of 90 minutes.

Vyxeos is part of a group of medicines called "antineoplastics" used against cancer. It contains two medicinal ingredients, daunorubicin and cytarabine, which are packaged in tiny particles known as liposomes. Vyxeos is believed to kill cancer cells by stopping them from growing and dividing. Packaging the medicinal ingredients in liposomes allows the drug to stay longer in the body. The liposome packaging also helps the drug enter the body and kill the cancer cells.

Vyxeos was researched and developed in British Columbia, Canada, through Celator Pharmaceuticals, a subsidiary of Jazz Pharmaceuticals since 2016. Vyxeos is the first product developed with Jazz Pharmaceuticals' CombiPlex® technology platform, which enables the delivery of the right proportion of drug ratios to a tumor site over a prolonged period of time.⁵

For more information, please refer to the product monograph for Vyxeos in Canada, located [here](#).

About AML

AML is a rare type of blood cancer that begins in the bone marrow and is characterized by the uncontrolled growth and division of abnormal myeloid cells.^{6,7,8} AML cells often move quickly from the bone marrow into the bloodstream, where they can spread to other parts of the body.⁹ The median age at diagnosis is 72 and AML prognosis progressively worsens with age.^{2,3} There is also reduced tolerance for intensive chemotherapy as patients age.^[10] People with t-AML or AML-MRC have some of the poorest survival rates of all AML types.^{2,3}

About CombiPlex


The CombiPlex technology evaluates drug combinations to identify the most effective, synergistic ratios that optimize anti-tumour activity.¹¹ It then

pairs this combination with an extremely small-scale (nanoparticle-size) delivery system that can be targeted directly at tumour tissues or cells.¹² CombiPlex utilizes two proprietary nano-scale delivery platforms: liposomes to control the release and distribution of water-soluble drugs and drugs that are both water- and fat-soluble (amphipathic), and nanoparticles to control the release and distribution of non-water-soluble (hydrophobic) drugs.⁹

About Jazz Pharmaceuticals plc

Jazz Pharmaceuticals plc (NASDAQ: JAZZ) is a global biopharmaceutical company whose purpose is to innovate to transform the lives of patients and their families. We are dedicated to developing life-changing medicines for people with serious diseases—often with limited or no therapeutic options. We have a diverse portfolio of marketed medicines and novel product candidates, from early- to late-stage development, in neuroscience and oncology. Within these therapeutic areas, we are identifying new options for patients by actively exploring small molecules and biologics, and through innovative delivery technologies and cannabinoid science. Jazz is headquartered in Dublin, Ireland and has employees around the globe, serving patients in nearly 75 countries. Please visit www.jazzpharmaceuticals.com for more information.

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SOURCE Jazz Pharmaceuticals Canada Inc