



Health Canada Approves Vyxeos®, the First Chemotherapy Advance in over 40 years for Adults with High-risk Acute Myeloid Leukemia (AML)

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DUBLIN, July 7, 2021 /CNW/ - Jazz Pharmaceuticals plc (NASDAQ: JAZZ) today announced the Health Canada approval and availability of Vyxeos® (daunorubicin and cytarabine liposome for injection) for the treatment of adults with newly diagnosed therapy-related AML (t-AML) or AML with myelodysplasia-related changes (AML-MRC).¹



AML, a cancer of the bone marrow and the blood, progresses rapidly without treatment.² Specifically, high-risk AML includes t-AML and AML-MRC.³ T-AML is caused by previous therapeutic treatments while AML-MRC occurs when there are certain changes in the bone marrow, which is the spongy tissue inside the bones.¹

Considered a rare disease, AML affects approximately 1,100 men and women in Canada annually.⁴ Though the number of AML cases has continued to rise⁵, the current treatment regimen for patients with high-risk AML has remained the same for decades until now.⁶

"Vyxeos is not only an effective treatment option but a significant advance by providing this patient population with a chemotherapy agent that takes less time to administer and provides a better chance at survival than our standard current treatment for high-risk AML," said Dr. Brian Leber, clinical hematologist, Juravinski Cancer Centre, Hamilton Health Sciences in Hamilton, Ontario. "Having more time is a substantial win for these 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.¹ The study met its primary endpoint as Vyxeos demonstrated a superior improvement in overall survival compared to the current conventional treatment group.¹ The median overall survival for the Vyxeos treatment group was 9.6 months compared with 6.0 months for the current conventional treatment group.¹

The most common adverse reactions ($\geq 10\%$ Incidence) attributed to Vyxeos are infection, febrile neutropenia, rash, transfusion reactions, sleep disorders, anxiety, delirium, headache, dizziness, visual impairment, non-conduction cardiotoxicity, arrhythmia, chest pain, hemorrhage, hypotension, hypertension, dyspnea, cough, pleural effusion, hypoxia, nausea, diarrhea/ colitis, mucositis, constipation, abdominal pain, decreased appetite, vomiting, hemorrhoids, pruritus, petechiae, musculoskeletal pain, renal insufficiency, edema, fatigue, chills, pyrexia and catheter/device/ injection site reaction.¹

"As a company dedicated to bringing life-changing medicines to market and redefining possibilities, the approval of Vyxeos in Canada represents Jazz's promise of putting patients first," said Paul Petrelli, general manager, Jazz Pharmaceuticals Canada Inc. "Vyxeos is an important example of how we meet the needs of the hematology and the oncology communities by offering a treatment that may extend life for high-risk AML patients."

Vyxeos is part of a group of medicines called "antineoplastics" used against cancer.¹ It contains two medicinal ingredients, daunorubicin and cytarabine,¹ which are packaged in tiny particles known as liposomes.¹ Vyxeos is believed to kill cancer cells by stopping them from growing and dividing.¹ Packaging the medicinal ingredients in liposomes allows the drug to stay longer in the body.¹ The liposomes packaging also helps the drug enter the body and kill the cancer cells.¹

About Vyxeos

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).¹

Vyxeos is administered by intravenous infusion over a period of 90 minutes.¹

Vyxeos liposomes accumulate and persist in the bone marrow where they are taken up intact by leukemia cells to a greater extent than by

non-leukemic bone marrow cells based on in-vivo animal studies.⁷

It is the first product to be developed with Jazz Pharmaceuticals' CombiPlex[®] technology platform, which uniquely enables the design, rapid evaluation and delivery of various combinations of therapies.⁸

Important Safety Information for Canada¹

Vyxeos should not be given to patients who are:

- allergic to daunorubicin or cytarabine, or to any of the other ingredients of this drug.

Vyxeos must be prescribed and administered to patients by specialized physicians experienced in the use of chemotherapeutic medicinal products." The most common side effects of Vyxeos are infection, febrile neutropenia, rash, transfusion reactions, sleep disorders, anxiety, delirium, headache, dizziness, visual impairment, non-conduction cardiotoxicity, arrhythmia, chest pain, hemorrhage, hypotension, hypertension, dyspnea, cough, pleural effusion, hypoxia, nausea, diarrhea/colitis, mucositis, constipation, abdominal pain, decreased appetite, vomiting, hemorrhoids, pruritus, petechiae, musculoskeletal pain, renal insufficiency, edema, fatigue, chills, pyrexia and catheter/device/ injection site reaction.¹

Vyxeos has different dosing directions than daunorubicin hydrochloride injection, cytarabine injection, daunorubicin citrate liposome injection and cytarabine liposome injection. Your healthcare professional will make sure you are getting the right drug and dose before giving you Vyxeos. If you think you may have received a different drug than usual, talk with your healthcare professional.

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

About AML²

AML is a rare type of blood cancer that begins in the bone marrow and blood. It damages the DNA (genetic material) of a developing stem cell in the bone marrow. This is called an "acquired mutation." Stem cells form blood cells (red cells, white cells and platelets). This damaged cell becomes a leukemic cell and multiplies into billions of cells called leukemic blasts that block the production of normal cells.

As a result, the number of healthy blood cells (red cells, white cells and platelets) is usually lower than normal and are crowded out by cancer or leukemic cells. The median age at diagnosis is 67. Symptoms may include but are not limited to pale skin, bruises with no clear cause and an enlarged liver or spleen. There is no known cause for most cases of AML.

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. We actively explore new options for patients including novel compounds, small molecules and biologics, and through cannabinoid science and innovative delivery technologies. Jazz is headquartered in Dublin, Ireland and has employees around the globe, serving patients in nearly 75 countries. For more information, please visit www.jazzpharmaceuticals.com and follow @JazzPharma on Twitter.

References

¹ Jazz Pharmaceuticals Canada Inc. Vyxeos[®] (daunorubicin and cytarabine liposome for injection) Product Monograph. April 28, 2021. Available at: <https://pp.jazzpharma.com/pi/vyxeos.ca.PM-en.pdf> Accessed May 30, 2021.

² LLSC. Acute Myeloid Leukemia. Available at: [https://www.llscanada.org/leukemia/acute-myeloid-leukemia#:~:text=Acute%20myeloid%20leukemia%20\(AML\).a%20difficult%20disease%20to%20treat](https://www.llscanada.org/leukemia/acute-myeloid-leukemia#:~:text=Acute%20myeloid%20leukemia%20(AML).a%20difficult%20disease%20to%20treat). Accessed May 31, 2021.

³ Russell N, Cluzeau T, McLornan D et al. Outcomes for Patients with High-Risk Acute Myeloid Leukaemia: Can We Move From Months to Years? Symposium and poster presentation at: EHA; June 11, 2020; Available at: <https://emj.emg-health.com/wp-content/uploads/sites/2/2020/07/Outcomes-for-Patients-with-High-Risk-Acute-Myeloid-Leukaemia-Can-We-Move-from-Months-to-Years.pdf>

⁴ Canadian Cancer Society. Acute Myelogenous Leukemia statistics. Available at: <https://www.cancer.ca/en/cancer-information/cancer-type/leukemia-acute-myelogenous-aml/statistics/?region=on#:~:text=Incidence%20and%20mortality&text=Mortality%20is%20the%20number%20of,diagnosed%20with%20acute%20myelogenous%20leukemia>. Accessed May 31, 2021.

⁵ Shysh, A.C., Nguyen, L.T., Guo, M. *et al.* The incidence of acute myeloid leukemia in Calgary, Alberta, Canada: a retrospective cohort study. BMC Public Health 18, 94 (2018). Available at: <https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-017-4644-6> Accessed May 31, 2021.

⁶ [Trialsitenews.com](https://trialsitenews.com/beat-aml-master-clinical-trial-shows-first-treatment-advance-in-40-years/). Beat AML Master Clinical Trial Shows First Treatment Advance in 40 Years. Available at: <https://trialsitenews.com/beat-aml-master-clinical-trial-shows-first-treatment-advance-in-40-years/> Accessed May 31, 2021.

⁷ [Vyxeos.com](https://vyxeospro.com/mechanism-of-delivery/). Mechanism of Delivery. Available at: <https://vyxeospro.com/mechanism-of-delivery/> Accessed May 31, 2021.

⁸ Tolcher AW, Mayer LD. Improving combination cancer chemotherapy: the CombiPlex[®] development platform. *Future Oncol.* 2018; 14(13), 1317-1332.

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