Misr International University
جامعة مصر الدولية

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Drug Information Newsletter

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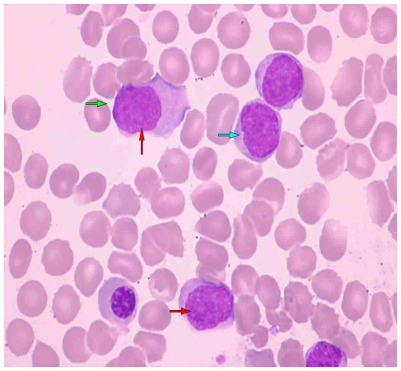
INSIDE THIS ISSUE:

FDA Approves Therapy to Treat Patients with Relapsed and Refractory Mantle Cell Lymphoma

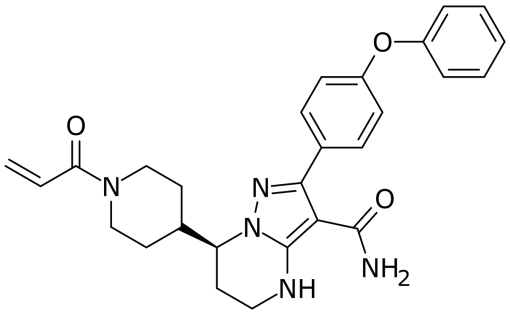


What Is Mantle Cell Lymphoma?

MCL is a type of "Non-Hodgkin's Lymphoma. It is a type of cancer that occurs due to changes in the B-cell lymphocytes. The affected lymphocytes may enter the patient's blood or lymph channels and spread to other lymph nodes. Also, metastasis can occur in other organs. In relapsed Lymphoma, the disease reappears after remission, while in refractory Lymphoma, the disease does not respond to treatment.[1]

Background Information about Brukinsa®

Brukinsa® (Zanubrutinib) inhibits malignant B-cell proliferation and reduces tumor growth by its Bruton tyrosine kinase (BTK) inhibition activity. It is indicated for adult patients having mantle cell lymphoma (MCL) and received at least 1 prior therapy. The recommended dose is 160 mg orally twice daily. The FDA granted Brukinsa® with Accelerated Approval, which enables the FDA to approve new medicines for serious conditions to meet a medical need.[2] Thus further clinical trials may be required to know Brukinsa's clinical benefit and all side effects. Like most neoplastic drugs, among the common adverse effects of Brukinsa® was decrease in blood picture count including platelet count, white blood cells count and hemoglobin. Also cardiac arrhythmias appeared in some patients. Patients are advised to use sun protection if taking this therapy because there is a risk of other malignancies occurring including skin cancers.



References:

1. *"Mantle Cell Lymphoma." Lymphoma Research Foundation, 2 Dec. 2021, https://lymphoma.org/aboutlymphoma/nhl/mcl/.*
2. *FDA Approves Treatment for Patients with Rare Bone marrow Disorder. U.S. Food and Drug Administration. Retrieved February 8, 2022, from https://www.fda.gov/news-events/press-announcements/fda-approves-treatment-patients-rare-bone-marrow-disorder*

The FDA advises the healthcare providers should tell their patients from both gender to use effective contraception during treatment with Brukinsa®. It is not advisable to give Brukinsa® to pregnant or breastfeeding women as it can cause problems for developing fetus or newborn baby[2].

ASCO/ASH Clinical Practice Guideline Update for Management of Cancer-Associated Anemia

Anemia is one of the most common side effects in patients suffering from cancer. In some cases, erythropoiesis – stimulating agents ESAs were recommended but ESAs can increase the incidence of thromboembolic events. Despite the risk of ESAs, these drugs are indicated in patients with cancer who are receiving chemotherapy with non-curative intent. ESAs are also indicated in patients suffering from anemia that cannot be adequately managed with blood transfusion. As this is an important topic that need regular updates, ASCO and ASH established an Expert Panel to review the evidence and revise previous recommendations. The panel conducted a systematic literature review of 15 meta-analyses and 2 randomized, controlled trials from 2010 to 2018.[1]

References

1. *Management of Cancer-Associated Anemia with ... - Asco.org. https://www.asco.org/sites/new-www.asco.org/files/content-files/practice-and-guidelines/documents/2019-ESAs-table.pdf.*

Question:

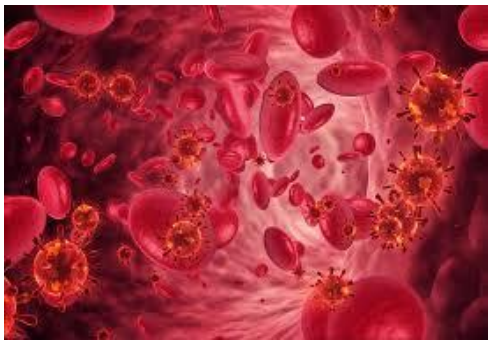
When and how erythropoiesis-stimulating agents (ESAs) should be used to manage anemia in adults with cancer?

Patient:

Adult patient suffering from cancer and anemia

Target health care givers:

Oncologist, hematologists, oncology clinical pharmacists



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Evidence of 5 selected guideline update recommendations

The first clinical question: Should ESAs be given to reduce blood transfusion for patients having chemotherapy-associated anemia?

- Recommendation: It depends on the clinical case ESAs may be offered for Chemotherapy associated anemia whose cancer treatment is not curative and where hemoglobin (HgB) has decreased to < 10 g/dL. RBC transfusion is also an option, depending on the severity of the anemia or clinical circumstances.[1]

(Evidence quality: high; strength of recommendation: strong).

The second selected clinical question: What examinations and diagnostic tests should be performed before making a decision about using an ESA to know the candidate patient?

- Recommendation: Before initiating ESAs, appropriate investigation must be done to identify the cause of anemia. Tests like peripheral blood smear, iron capacity, vitamin B, ferritin, transferrin saturation, and baseline erythropoietin level should be done.

(Evidence quality: intermediate; strength of recommendation: strong).

Third clinical question: For the patients who receive ESA for chemotherapy-associated anemia, are Darbepoetin, Epoetin Beta and Alfa originator considered bio-similar with respect to efficacy and safety?

- Recommendation: The experts said that the previous drugs are considered to be equivalent in efficacy and safety

(Evidence quality: intermediate; strength of recommendation: moderate).

Fourth clinical question Do ESAs increase the risk of thromboembolism?

- Recommendation: Experts said that ESAs increase the risk of thromboembolism, and before initiating ESAs risk- benefits should be balanced by clinicians and it should be used with caution.

(Evidence quality: high; strength of recommendation: strong)

Fifth clinical question in patient receiving ESA with chemotherapy-associated anemia does adding iron supplementation concurrent with an ESA reduce transfusion requirements?

- Recommendation: Experts announced that replacement may be used to improve Hemoglobin level and reduce RBC transfusions for patients receiving ESA with or without iron deficiency. However, baseline and monitoring of iron, total iron-binding capacity, transferrin saturation, or ferritin levels are recommended.

(Evidence quality: intermediate; strength of recommendation: weak).[2]

References

1. *"Article Tools." Journal of Clinical Oncology, https://ascopubs.org/doi/full/10.1200/JCO.18.02142.*
2. *Bohlius, J., Bohlke, K., Castelli, R., Djulbegovic, B., Lustberg, M. B., Martino, M., Mountzios, G., Peswani, N., Porter, L., Tanaka, T. N., Trifirò, G., Yang, H., & Lazo-Langner, A. (2019, April 10). Management of Cancer-Associated Anemia with Erythropoiesis-Stimulating Agents: ASCO/ash Clinical Practice Guideline Update. American Society of Hematology. Retrieved February 8, 2022, from https://ashpublications.org/bloodadvances/article/3/8/1197/260121/Management-of-cancer-associated- anemia-with*