Jylamvo® (methotrexate) – New drug approval

- On November 29, 2022, the FDA approved Therakind's Jylamvo (methotrexate) oral solution, for the treatment of:
    - Adults with acute lymphoblastic leukemia (ALL) as part of a combination chemotherapy maintenance regimen
    - Adults with mycosis fungoides (cutaneous T-cell lymphoma) as a single agent or as part of a combination chemotherapy regimen
    - Adults with relapsed or refractory non-Hodgkin lymphomas as part of a metronomic combination chemotherapy regimen
    - Adults with rheumatoid arthritis
    - Adults with severe psoriasis.

- Methotrexate is available generically in oral and injectable formulations and as another branded oral solution (Xatmep®).
    - The indications for Jylamvo are shared by the oral tablet formulations of methotrexate.
    - Xatmep is approved for treatment of pediatric patients with ALL as a component of a combination chemotherapy maintenance regimen and management of pediatric patients with active polyarticular juvenile idiopathic arthritis who are intolerant of or had an inadequate response to first-line therapy.

- Jylamvo carries a boxed warning for embryo-fetal toxicity, hypersensitivity reactions, and severe adverse reactions.

- Jylamvo is contraindicated in:
    - Pregnant women for treatment of non-neoplastic diseases
    - Patients with a history of a severe hypersensitivity reactions, including anaphylaxis, to methotrexate.

- Refer to the Jylamvo drug label for a complete list of the warnings and precautions.

- The most common adverse reactions with Jylamvo use were ulcerative stomatitis, leukopenia, nausea, and abdominal distress.

- The recommended dosing of Jylamvo depends on the indication or use.
    - ALL: The recommended starting dosage is 20 mg/m^2 orally once weekly, as part of a combination chemotherapy maintenance regimen. After initiating treatment, absolute neutrophil count (ANC) and platelet count should be periodically monitored, and the dose adjusted to maintain ANC at a desirable level and for excessive myelosuppression.
    - Mycosis fungoides: The recommended dosage is 25 to 75 mg orally once weekly when administered as a single agent or 10 mg/m^2 orally twice weekly as part of a combination chemotherapy regimen.
    - Relapsed or refractory non-Hodgkin lymphomas: The recommended dosage is 2.5 mg orally 2 to 4 times per week (maximum 10 mg per week) as part of a metronomic combination chemotherapy regimen.

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  - — Rheumatoid arthritis: The recommended starting dosage is 7.5 mg orally once weekly with escalation to achieve optimal response. Dosages of more than 20 mg once weekly result in an increased risk of serious adverse reactions.
  - — Psoriasis: The recommended dosage is 10 to 25 mg orally once weekly until an adequate response is achieved. The dose should be adjusted gradually to achieve optimal clinical response and should not exceed a dose of 30 mg per week. Once optimal clinical response has been achieved, the dosage should be reduced to the lowest possible dosing regimen.

- Therakind's launch plans for Jylamvo are pending. Jylamvo will be available as a 2 mg/mL oral solution.