Vyxeos® (daunorubicin and cytarabine) – Expanded indication

- On March 30, 2021, Jazz Pharmaceuticals announced the FDA approval of Vyxeos (daunorubicin and cytarabine), for the treatment of newly-diagnosed therapy-related acute myeloid leukemia (t-AML) or acute myeloid leukemia with myelodysplasia-related changes (AML-MRC) in adults and pediatric patients 1 year and older.
    - Vyxeos was previously approved for these indications in adults only.
- The approval of Vyxeos for the expanded indication was based on two single-arm trials evaluating the pharmacokinetics and safety of Vyxeos in children and young adults. Study AAML1421 evaluated 38 patients aged 1 to 21 years with AML in first relapse and study CPX-MA-1201 evaluated 27 patients aged 1 to 19 years with relapsed/refractory hematologic malignancies. Both studies did not find any differences in the safety profile by age. The efficacy of Vyxeos for patients aged 1 year and older was extrapolated from the pivotal trial in adults.
- Vyxeos has a boxed warning stating it should not be interchanged with other daunorubicin- and/or cytarabine-containing products.
- The recommended dosage of Vyxeos in pediatric patients is identical to current dosing recommendations for adults.
- Refer to the Vyxeos drug label for complete dosing and administration recommendations