Tepadina® (thiotepa) – New Drug Approval

- On January 26, 2017, the FDA approved Adienne's Tepadina (thiotepa) for the following indications:
    - To reduce the risk of graft rejection when used in conjunction with high-dose busulfan (Busulfex®) and cyclophosphamide as a preparative regimen for allogeneic hematopoietic progenitor (stem) cell transplantation (HSCT) for pediatric patients with class 3 beta-thalassemia
    - For treatment of adenocarcinoma of the breast or ovary
    - For controlling intracavitary effusions secondary to diffuse or localized neoplastic diseases of various serosal cavities
    - For treatment of superficial papillary carcinoma of the urinary bladder
- Thiotepa is also generically available as a 15 mg vial. Thiotepa shares Tepadina's indications except for class 3 beta-thalassemia. In addition, while largely superseded by other treatments, thiotepa has been effective against other lymphomas, such as lymphosarcoma and Hodgkin's disease.
- The efficacy of Tepadina for pediatric patients with class 3 beta-thalassemia who underwent allogeneic HSCT was evaluated in a retrospective study of 25 patients.
    - The incidence of graft rejection was 0% (95% CI: 0, 0.12).
    - In 51 patients who received the same preparative regimen, historically, without Tepadina, the incidence of graft rejection reported was 25.5% (95% CI: 0.13, 0.37).
- Tepadina carries a boxed warning for severe myelosuppression and carcinogenicity.
- Tepadina is contraindicated in patients with severe hypersensitivity to thiotepa and concomitant use with live or attenuated vaccines.
- Other warnings and precautions of Tepadina include cutaneous toxicity, hepatic veno-occlusive disease, central nervous system toxicity, and embryo-fetal toxicity.
- The most common adverse events (> 10%) with Tepadina use were neutropenia, anemia, thrombocytopenia, elevated alanine aminotransferase, elevated aspartate aminotransferase, elevated bilirubin, mucositis, cytomegalovirus infection, hemorrhage, diarrhea, hematuria and rash.
- Tepadina is dosed according to body weight.
    - For class 3 beta-thalassemia and adenocarcinoma of the breast or ovary, Tepadina is administered intravenously.
    - For malignant effusions, Tepadina is administered by the intracavitary route.
    - For papillary carcinoma of the urinary bladder, Tepadina is administered into the bladder by catheter.
    - For further details, Tepadina's prescribing information should be consulted for dosing in each indication.

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- Adienne's launch plans for Tepadina are pending. Tepadina will be available as 15 mg and 100 mg vials.