Hydroxyurea (Droxia®, Hydrea®) – New Warnings

- The FDA approved new updates to the Warnings and Precautions section of the hydroxyurea (Droxia, Hydrea) drug labels with regards to embryo-fetal toxicity and vaccination information.
  - Droxia is indicated to reduce the frequency of painful crises and to reduce the need for blood transfusions in patients with sickle cell anemia with recurrent moderate to severe painful crises.
  - Hydrea is indicated for the treatment of resistant chronic myeloid leukemia and locally advanced squamous cell carcinomas of the head and neck (excluding the lip) in combination with chemoradiation.

- Based on the mechanism of action and findings in animals, hydroxyurea can cause fetal harm when administered to a pregnant woman. Pregnant women should be advised of the potential risk to a fetus.
  - Women and men of reproductive potential should be advised to use effective contraception during and after hydroxyurea therapy (women: ≥ 6 months post therapy; men: ≥ 1 year post therapy).

- Use of live vaccines should be avoided in patients taking hydroxyurea. Concomitant use of hydroxyurea with a live virus vaccine may potentiate the replication of the virus and/or may increase the adverse reaction of the vaccine because normal defense mechanisms may be suppressed by hydroxyurea therapy.
  - Vaccination with live vaccines in a patient receiving hydroxyurea may result in severe infection. Patient’s antibody response to vaccines may be decreased. Consultation with a specialist may be considered.

- Other warnings and precautions of hydroxyurea include myelosuppression, malignancies, vasculitis toxicities, risks with concomitant use of antiretroviral drugs, radiation recall, and macrocytosis.