Heplisav-B™ (hepatitis B vaccine) – New drug approval

- On November 9, 2017, Dynavax announced the FDA approval of Heplisav-B (hepatitis B vaccine [recombinant] adjuvanted), for the prevention of infection caused by all known subtypes of hepatitis B virus.
    - Heplisav-B is approved for use in adults 18 years of age and older.
- Hepatitis B is viral disease of the liver that can become chronic and lead to cirrhosis, liver cancer, and death. The hepatitis B virus is 50 to 100 times more infectious than the human immunodeficiency virus (HIV) and its transmission is on the rise.
    - There is no cure for hepatitis B, but effective vaccination can prevent the disease.
    - The Centers for Disease Control and Prevention (CDC) recommends vaccination for those at high risk for infection due to their jobs, lifestyle, living situations, and travel to certain areas. Because diabetes patients are particularly vulnerable to infection, the CDC recommends vaccination for adults 19 to 59 years of age with diabetes, and for people ≥ 60 years old with diabetes at their physician's discretion.
- Heplisav-B is an adult hepatitis B vaccine that combines hepatitis B surface antigen with a proprietary Toll-like receptor 9 agonist to enhance the immune response.
- The approval of Heplisav-B was based on three non-inferiority trials comparing Heplisav-B administered in two doses over one month to Engerix-B® (hepatitis B vaccine [recombinant]) administered in three doses over a six-month schedule.
    - In all three trials, Heplisav-B met the non-inferiority seroprotection endpoint.
- Heplisav-B is contraindicated in patients with a history of severe allergic reactions (eg, anaphylaxis) after a previous dose of any hepatitis B vaccine or to any component of Heplisav-B, including yeast.
- Warnings and precautions of Heplisav include managing allergic reactions, immunocompromised individuals, and limitations of vaccine effectiveness.
- The most common local reactions (23% – 39%) with Heplisav-B use was injection site pain.
- The most common systemic reactions with Heplisav-B use were fatigue (11% – 17%) and headache (8% – 17%).
- The recommended dosage of Heplisav-B is two doses (0.5 mL each) by intramuscular injection in the deltoid region given one month apart.
- Dynavax plans to launch Heplisav-B in the first quarter of 2018. Heplisav-B will be available in single-dose vials for injection.