Shingrix (Zoster vaccine recombinant, adjuvanted) – Expanded indication

- On July 26, 2021, GlaxoSmithKline announced the FDA approval of Shingrix (Zoster vaccine recombinant, adjuvanted), for prevention of herpes zoster (HZ) (shingles) in adults aged 18 years and older who are or will be at increased risk of HZ due to immunodeficiency or immunosuppression caused by known disease or therapy.
    - Shingrix is not indicated for prevention of primary varicella infection (chickenpox).
- Shingrix is also approved for the prevention of HZ in adults aged 50 years and older.
- The approval of Shingrix for the expanded indication was based on a randomized, placebo-controlled, observer-blind clinical study in immunocompromised adults aged ≥ 18 years who received an autologous hematopoietic stem cell transplant (auHSCT) 50 to 70 days prior to dose 1 and who were expected to receive prophylactic antiviral therapy for ≤ 6 months post-transplant. The primary efficacy analysis population included 1,721 subjects who received 2 doses of either Shingrix or placebo and did not develop a confirmed case of HZ within 1 month after the second dose.
    - The incidence rate of HZ per 1,000 person-years was 30.0 with Shingrix vs. 94.3 with placebo (% efficacy: 68.2, 95% CI: 55.5, 77.6).
- The efficacy was also calculated post-hoc in another randomized, placebo-controlled, observer-blind study in patients with hematologic malignancies who received dose 1 of Shingrix or placebo during or within 6 months of completing immunosuppressive chemotherapy. The population for the post hoc efficacy analysis included 515 subjects who received 2 doses of either Shingrix or placebo and did not develop a confirmed case of HZ within 1 month after the second dose.
    - The post hoc analysis showed Shingrix was 87.2% (95% CI: 44.2, 98.6) effective against development of HZ. The incidence rate of HZ per 1,000 person-years was 8.5 vs. 66.2 in the Shingrix and placebo groups, respectively.
- Solicited local adverse reactions reported in auHSCT recipients (aged 18 to 49 and ≥ 50 years of age) were pain, redness, and swelling.
- Solicited general adverse reactions reported in auHSCT recipients (aged 18 to 49 and ≥ 50 years of age) were fatigue, myalgia, headache, gastrointestinal symptoms, shivering, and fever.
- Shingrix is administered as two doses (0.5 mL each) intramuscularly according to the following schedules:
    - A first dose at month 0 followed by a second dose administered 2 to 6 months later.
    - For individuals who are or will be immunodeficient or immunosuppressed and who would benefit from a shorter vaccination schedule: a first dose at month 0 followed by a second dose administered 1 to 2 months later.