Penmenvy (meningococcal groups A, B, C, W, and Y vaccine) – New vaccine approval

- On February 15, 2025, GSK announced the FDA approval of Penmenvy (meningococcal groups A, B, C, W, and Y vaccine), for **active immunization to prevent invasive disease caused by *Neisseria meningitidis* serogroups A, B, C, W, and Y in individuals 10 through 25 years of age**.
- The vaccine targets five major serogroups of *Neisseria meningitidis* (A, B, C, W, and Y) which commonly cause invasive meningococcal disease.
- The approval of Penmenvy was supported by positive results from two studies, which evaluated the vaccine's safety, tolerability, and immune response in over 4,800 participants aged 10 to 25 years.
- Warnings and precautions for Penmenvy include management of allergic reactions, syncope, limitation of vaccine effectiveness, altered immunocompetence, and Guillain-Barré syndrome.
- The most common solicited adverse reactions (≥ 10%) with Penmenvy use after dose 1 and 2, respectively:
    - In individuals aged 10 through 25 years were pain at the injection site, fatigue, headache, myalgia, nausea, erythema, and swelling.
    - In MenACWY conjugate vaccine-experienced individuals aged 15 through 25 years were pain at the injection site, headache, fatigue, myalgia, and nausea.
- Penmenvy is administered as 2 doses (approximately 0.5 mL each) 6 months apart.
- At its meeting on February 26, 2025, the CDC's Advisory Committee on Immunization Practices (ACIP) is expected to vote on recommendations for the appropriate use of Penmenvy in adolescents and young adults.
- GSK's launch plans for Penmenvy are pending. Penmenvy will be available as a powder in a vial (reconstituted to 0.5 mL injectable suspension).