RotaTeq® (rotavirus vaccine, live, oral, pentavalent) – Expanded indication

- On February 23, 2017, the FDA approved Merck's RotaTeq (rotavirus vaccine, live, oral, pentavalent), to include prevention of rotavirus gastroenteritis in infants and children caused by type G9 when administered as a 3-dose series to infants between the ages of 6 – 32 weeks.
    - Previously, RotaTeq was only approved for types G1, G2, G3, and G4.
    - The first dose of RotaTeq should be administered between 6 and 12 weeks of age.
- The approval of RotaTeq's expanded indication was based on additional analysis conducted to evaluate efficacy in the prevention of rotavirus gastroenteritis. G9P1A-associated gastroenteritis was observed in 0 out of 356 subjects vs. 5 out of 356 subjects in the placebo group (100%, [95% CI: -9.0, 100.0]).
    - Furthermore, in a post hoc analysis of health care utilization data involving 68,038 infants, cases due to type G9P1A were reduced by 100% with RotaTeq vs. placebo (0 cases vs. 14 cases, [95% CI: 69.6, 100.0]).
- RotaTeq consists of three ready-to-use liquid doses administered orally starting at 6 – 12 weeks of age, with subsequent doses administered at 4 – 10 week intervals. The third dose should not be given after 32 weeks of age.