Vancomycin – New formulation approval

- On February 19, 2019, Xellia Pharmaceuticals announced the FDA approval of vancomycin premixed injection.

- Vancomycin is approved in adult and pediatric patients (1 month and older) for the treatment of susceptible organisms in the following:

  - Septicemia
  - Infective endocarditis
  - Skin and skin structure infections
  - Bone infections
  - Lower respiratory tract infections
  - Consult the vancomycin drug label for details about the susceptible organisms.

- Vancomycin injection, ready to use (RTU) is a proprietary formulation of vancomycin, provided as a premixed solution in single-dose flexible bags, stable at room temperature for 16 months.

- Vancomycin is also available generically as a capsule and an intravenous solution for reconstitution, and a brand oral solution (Firvanq™).

  - Oral vancomycin capsules and Firvanq are indicated for the treatment of *Clostridium difficile*-associated diarrhea (CDAD) and enterocolitis caused by *Staphylococcus aureus* (including methicillin-resistant strains).
  - Vancomycin intravenous solution carries the same indications as vancomycin premixed injection. This formulation may also be used orally for CDAD and enterocolitis.

- The FDA approval of this novel vancomycin formulation was obtained on the basis of more than 60 non-clinical experiments, including studies to confirm that the new formulation does not adversely impact the efficacy profile of the active ingredient, vancomycin.

- Vancomycin carries a boxed warning for risk of embryo-fetal toxicity due to excipients.

- Additional warnings and precautions of vancomycin include infusion reaction, nephrotoxicity, ototoxicity, CDAD, hemorrhagic occlusive retinal vasculitis, neutropenia, phlebitis and other administration site reactions, and development of drug-resistant bacteria.

- The most common adverse reactions of vancomycin use were anaphylaxis, “red man syndrome”, acute kidney injury, hearing loss, neutropenia.

- The recommended adult dose of vancomycin is 2 grams intravenously (IV) divided either as 500 mg every 6 hours or 1 gram every 12 hours infused over 60 minutes or greater.

  - The recommended pediatric dose of vancomycin is 10 mg/kg per dose IV every 6 hours infused over a period of at least 60 minutes.
  - This formulation of vancomycin injection should only be used in patients who require the entire (500 mg, 1 gram, 1.5 grams or 2 grams) dose and not any fraction thereof.
  - This formulation of vancomycin injection should not be used orally.

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- Xellia Pharmaceuticals' launch plans for vancomycin injection are pending. Vancomycin RTU will be available as 500 mg in 100 mL, 1 gram in 200 mL, 1.5 grams in 300 mL, and 2 grams in 400 mL of liquid in single-dose flexible bags.