Triferic AVNU® (ferric pyrophosphate citrate) – New formulation approval

- On March 27, 2020, Rockwell Medical announced the FDA approval of Triferic AVNU (ferric pyrophosphate citrate), an iron replacement product, for the replacement of iron to maintain hemoglobin in adult patients with hemodialysis-dependent chronic kidney disease (HDD-CKD).
    - Triferic is not intended for use in patients receiving peritoneal dialysis.
    - Triferic has not been studied in patients receiving home hemodialysis.
- Triferic AVNU is designed for direct intravenous (IV) infusion and can be administered regardless of a dialysis center's mode of bicarbonate delivery. In contrast, Rockwell's other ferric pyrophosphate citrate product (Triferic®) is designed to be administered via liquid bicarbonate.
- Warnings and precautions for Triferic AVNU include hypersensitivity reactions and iron laboratory testing.
- The most common adverse reactions (≥ 3%) with Triferic AVNU use were headache, peripheral edema, asthenia, AV fistula thrombosis, urinary tract infection, AV fistula site hemorrhage, pyrexia, fatigue, procedural hypotension, muscle spasms, pain in extremity, back pain, and dyspnea.
- The recommended dose of Triferic AVNU is 6.75 mg iron (III) undiluted as a slow continuous IV infusion over 3 to 4 hours via the pre-dialyzer infusion line, post-dialyzer infusion line, or via a separate connection to the venous blood line during hemodialysis.
    - Triferic AVNU should be administered at each dialysis procedure for as long as patients are receiving maintenance hemodialysis therapy for CKD.
    - The dosage of Triferic AVNU solution is expressed as mg of iron (III). Each mL of Triferic AVNU injection for IV administration contains 1.5 mg iron as iron (III).
- Rockwell Medical launch plans for Triferic AVNU are pending. Triferic AVNU will be available as a 6.75 mg iron (III) per 4.5 mL solution in single-dose luer lock ampule