

Drug Pipeline MONTHLY UPDATE

Critical updates in an ever-changing environment

April 2020

NEW DRUG INFORMATION

- **Triferic Avnu™ (ferric pyrophosphate citrate):** The U.S. Food and Drug Administration (FDA) approved Rockwell Medical's Triferic Avnu, an iron replacement product, to maintain hemoglobin in adults with hemodialysis-dependent chronic kidney disease (HDD-CKD). Triferic Avnu joins Rockwell Medical's Triferic Dialysate (liquid bicarbonate administration) as the only FDA-approved products indicated to replace iron and maintain hemoglobin in adult patients with HDD-CKD. Triferic Avnu is administered via intravenous infusion regardless of a dialysis center's mode of bicarbonate delivery.¹ Rockwell plans to launch Triferic Avnu closer to the third quarter in 2020, with pricing information to follow.

GENERIC DRUG INFORMATION

- **Nexium® (esomeprazole):** Cipla launched their generic version of AstraZeneca's Nexium granules for the treatment of gastroesophageal reflux disease (GERD) and gastric ulcer. No exclusivities remain for Nexium granules. Nexium granules generated \$43 million in U.S. annual sales in 2019.
- **Tepadina® (thiotepa):** Amneal Biosciences launched their generic version of Adienne's Tepadina for the treatment of certain forms of cancer. Tepadina generated \$24 million in U.S. annual sales in 2019.
- **Proventil HFA® (albuterol HFA):** Cipla launched their generic version of Merck's Proventil HFA for treatment of asthma, COPD and shortness of breath. Cipla's generic version of Proventil HFA is the first FDA-approved, therapeutically equivalent, albuterol sulfate HFA inhaler. It is unclear whether any additional exclusivities remain for Proventil HFA. Proventil-HFA had annual U.S. sales of \$105 million in 2019. ProAir HFA®, an additional substitutable version of Proventil-HFA (albuterol sulfate HFA 108mcg/act), had annual U.S. sales of \$1.4 billion in 2019.

REFERENCES

1. <https://www.globenewswire.com/news-release/2020/03/27/2007742/0/en/Rockwell-Medical-Inc-Received-FDA-Approval-for-Triferic-AVNU-Ferric-Pyrophosphate-Citrate-Intravenous-Formulation-of-Triferic-for-Replacement-of-Iron-and-Maintenance-of-Hemoglobin-.html>

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