New drug information

- **Vermox® (mebendazole):** The Food and Drug Administration (FDA) approved Johnson & Johnson/Janssen’s Vermox for parasitic disease. Vermox is available as a 500 mg chewable single dose tablet for patients 1 year of age and older. Similar products by indication include Amedra’s Emverm™ (mebendazole) 100 mg chewable tablet. Emverm has been studied in patients 2 years of age and older; the dose depends on the parasitic infection being treated.

- **Vemlidy® (tenofovir alafenamide):** The FDA approved Gilead’s Vemlidy for the treatment of chronic hepatitis B virus (HBV) infection in adults with compensated liver disease. Similar products by indication include Gilead’s Viread® (tenofovir disoproxil fumarate) which is approved for use in patients with HBV 12 years of age and older; as well as for the treatment of HIV. These tenofovir products differ only by the salt which allows the dose of Vemlidy to be lower at 25 mg versus Viread at 300 mg. As a result, Vemlidy is similar in efficacy to Viread, but Vemlidy may improve renal and bone laboratory safety parameters compared to Viread.

- **Bonjesta® (20 mg doxylamine/20 mg pyridoxine extended-release [XR]):** The FDA approved Duchesnay’s Bonjesta for pregnancy-related nausea and vomiting in women who do not respond to conservative management. Duchesnay also markets Diclegis® which contains 10 mg of doxylamine succinate and 10 mg of pyridoxine delayed release tablets (10mg/10 mg) for the same indication. Both products are started at 20 mg/20 mg once daily and can increase the dose to a maximum of 40 mg/40 mg total per day. Doxylamine, an antihistamine, and pyridoxine, a vitamin B6 analog, are both available individually over-the-counter (OTC).

- **Intrarosa® (prasterone):** The FDA approved Endoceutics Inc.’s Intrarosa, a once-daily vaginal insert, for the treatment of moderate-to-severe pain during sex in post-menopausal women. Intrarosa is the first FDA-approved product containing the active ingredient prasterone, also known as dehydroepiandrosterone (DHEA).

- **Xultophy® (Tresiba® (insulin degludec)/Victoza® (liraglutide)):** The FDA approved NovoNordisk’s Xultophy as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus inadequately controlled on basal insulin (less than 50 units daily) or liraglutide (less than or equal to 1.8 mg daily). Xultophy is injected subcutaneously once daily at the same time each day with or without food. Xultophy will be launched in the first half of 2017.

- **Soliqua™ (Lantus® (insulin glargine)/Adlyxin™ (lixisenatide)):** The FDA also approved Sanofi’s Soliqua as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus inadequately controlled on basal insulin (less than 60 units daily) or lixisenatide. Soliqua is injected subcutaneously once a day within the hour prior to the first meal of the day. Soliqua will be launched in January 2017.

Xultophy and Soliqua are the first combinations of basal insulin and glucagon-like peptide-1 (GLP-1) receptor agonists. Sanofi said that Soliqua would be priced on par with solo GLP-1s in the U.S. Novo Nordisk said it’s planning a list price that is 20 percent lower than the combined cost of Victoza and Tresiba, and will negotiate payer discounts from there. Analysts have estimated the market for Xultophy as a $1.2 billion drug by 2021, and Soliqua at up to $960 million by 2022.¹
New generics

- **Benicar® (olmesartan):** Mylan has launched a generic version of Daiichi Sankyo’s Benicar for the treatment of hypertension. Mylan will have 180 days of marketing exclusivity. According to IMS, Benicar had approximately $1 billion in U.S. annual sales. After the exclusivity period, 11 additional manufacturers are anticipated to launch their generic version of Benicar.

- **Benicar HCT® (olmesartan/hydrochlorothiazide):** Mylan has launched a generic version of Daiichi Sankyo’s Benicar HCT for the treatment of hypertension. Mylan will have 180 days of marketing exclusivity. According to IMS, Benicar HCT had approximately $805 million in U.S. annual sales. After the exclusivity period, four additional manufacturers are anticipated to launch their generic version of Benicar HCT.

- **Azor® (amlodipine/olmesartan):** Multiple generic manufacturers, including Teva, Sun, and Ajanta, have launched the generic version of Daiichi Sankyo’s Azor for the treatment of hypertension. According to IMS data, Azor had annual sales of approximately $354 million in the U.S.

- **Tribenzor® (olmesartan/amlodipine/hydrochlorothiazide):** Both Sun and Par have launched the generic version of Daiichi Sankyo’s Tribenzor for the treatment of hypertension. According to IMS data, Tribenzor had annual sales of approximately $240 million in the U.S.

- **Seroquel XR® (quetiapine fumarate SR):** Par Pharmaceutical has launched an authorized generic version of AstraZeneca’s Seroquel XR in the strength of 50 mg, 150 mg, 200 mg, and 300 mg for the treatment of major depressive disorder, schizophrenia and bipolar disorder. ANDA-approved generics are expected after the exclusivity period of 180 days expires. According to IMS, Seroquel XR had $911 million in annual U.S. sales for the four dosage strengths to be marketed by Par.

- **Sarafem® (fluoxetine):** Torrent Pharmaceuticals has launched a generic version of Actavis’s Sarafem for the treatment of premenstrual dysphoric disorder (PMDD). This is the first generic for Sarafem tablets, however, generic Sarafem capsules have been available since 2008.

References

1. [http://www.fiercepharma.com/pharma/it-s-simultaneous-fda-nods-sanofi-and-novo-to-vie-for-combo-med-supremacy?utm_medium=nl&utm_source=internal&mkid=36641180&mktk_token=eyJpIjoiTnpnNFltVmpPVEZpKRWaS1nNQ0Q00QZlZkN2ZjdMTU0WHyYkhlbmdsbGhlYmVsaW1lci1hYXN0b3J5IjoiM2RiN2RiOTUwYzdhNjM1N2U0N2E1YzU4YzY1N2VlZjUzNzY5M2IzMjY1M2EwZmIyZjIwMWE5Yy0yMDIzNjE4YjYuanBuIi14YW5kZGR2cDhiOTU2MjQ3Mzc4OTJhMzkxZjM1MDU5ODgwZDFlOTk2MjUxNjYwNDA3NjMzY2E1NzE1OTEyZmUwZmJhNWRlZjY3ZGU0Njk4ZOlzIiwicjJlZ05teF9pY2FsbWV0aG9kZXIiOlwiNDk2NTI0NjU0YzYyZjFiMDY4MjJiNTQ2MTU5ZjE5ZmY4MDU2NjRhODIzZDQwYWVhZDIzYjZiODI1MjczMzRlN2M0MTM3ZjgiLCJodHR0Yi00NDY2MDZhNTBiM2FjZjJkYmUyZWRlNzIwZDQ4YzI3OTZlZmViMjI2NDM5NjY3ZjA5OTI0ZjNhZTVlOTFhNzEtYmJhZi00N2RiLThmN2JjYzI1ZjAyOWI0YmRiYjY4ZTY5OTc5MGI5MjY1MmZiNjI3ZmJiNTUxYmYzOTZiZmE0ZTYzN2MyM2JiZiJ9](http://www.fiercepharma.com/pharma/it-s-simultaneous-fda-nods-sanofi-and-novo-to-vie-for-combo-med-supremacy?utm_medium=nl&utm_source=internal&mkid=36641180&mktk_token=eyJpIjoiTnpnNFltVmpPVEZpKRWaS1nNQ0Q00QZlZkN2ZjdMTU0WHyYkhlbmdsbGhlYmVsaW1lci1hYXN0b3J5IjoiM2RiN2RiOTUwYzdhNjM1N2U0N2E1YzU4YzY1N2VlZjUzNzY5M2IzMjY1M2EwZmIyZjIwMWE5Yy0yMDIzNjE4YjYuanBuIi14YW5kZGR2cDhiOTU2MjQ3Mzc4OTJhMzkxZjM1MDU5ODgwZDFlOTk2MjUxNjYwNDA3NjMzY2E1NzE1OTEyZmUwZmJhNWRlZjY3ZGU0Njk4ZOlzIiwicjJlZ05teF9pY2FsbWV0aG9kZXIiOlwiNDk2NTI0NjU0YzYyZjFiMDY4MjJiNTQ2MTU5ZjE5ZmY4MDU2NjRhODIzZDQwYWVhZDIzYjZiODI1MjczMzRlN2M0MTM3ZjgiLCJodHR0Yi00NDY2MDZhNTBiM2FjZjJkYmUyZWRlNzIwZDQ4YzI3OTZlZmViMjI2NDM5NjY3ZjA5OTI0ZjNhZTVlOTFhNzEtYmJhZi00N2RiLThmN2JjYzI1ZjAyOWI0YmRiYjY4ZTY5OTc5MGI5MjY1MmZiNjI3ZmJiNTUxYmYzOTZiZmE0ZTYzN2MyM2JiZiJ9)

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