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PharmNOTES

Summary about new FDA products,
generic medication, medical products,
and WHAT IS IN THE PIPELINE.

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Pharmacy Benefit Management
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NEWS……

- No security warning published during January 2019.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Ontruzant™ (trastuzumab-dttb) for Injection, for intravenous use / Samsung Bioepis Co., Ltd.	Antineoplastic agent HER2/neu receptor antagonist Note: Biosimilar to Herceptin™	Treatment of: • HER2-overexpressing breast cancer • HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma	01/18/2019	**DOSAGE AND ADMINISTRATION** For Adjuvant Treatment of HER2-Overexpressing Breast Cancer: • Initial dose of 4 mg/kg over 90 minute IV infusion, then 2 mg/kg over 30 minute IV infusion weekly for 12 weeks (with paclitaxel or docetaxel) or 18 weeks (with docetaxel and carboplatin). One week after the last weekly dose of Ontruzant, administer 6 mg/kg as an IV infusion over 30 to 90 minutes every three weeks to complete a total of 52 weeks of therapy, or • Initial dose of 8 mg/kg over 90 minutes IV infusion, then 6 mg/kg over 30 to 90 minutes IV infusion every three weeks for 52 weeks. For Metastatic HER2-Overexpressing Breast Cancer: • Initial dose of 4 mg/kg as a 90 minute IV infusion followed by subsequent weekly doses of 2 mg/kg as 30 minute IV infusions. For Metastatic HER2-Overexpressing Gastric Cancer: • Initial dose of 8 mg/kg over 90 minutes IV infusion, followed by 6 mg/kg over 30 to 90 minutes IV infusion every 3 weeks. Select patients for therapy based on an FDA-approved companion diagnostic for a trastuzumab product. Do not substitute Ontruzant (trastuzumab-dttb) for or with ado-trastuzumab emtansine. **DOSAGE FORMS AND STRENGTHS** For Injection: 150 mg lyophilized powder in a single-dose vial for reconstitution. **CONTRAINDICATIONS** None. **WARNINGS AND PRECAUTIONS** • Exacerbation of chemotherapy-induced neutropenia.

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New FDA Approved Indications

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Cabometyx™ (cabozantinib) Tablets / Exelixis, Inc.	Antineoplastic agent; Tyrosine kinase inhibitor	**Previous indication(s):** Treatment of advanced renal cell carcinoma (RCC) **New indication:** For hepatocellular carcinoma (HCC) who have been previously treated with sorafenib	01/14/2019	This approval was based on results from the CELESTIAL phase 3 pivotal trial of Cabometyx™ for patients with advanced HCC who received prior sorafenib. Cabometyx™ demonstrated a statistically significant and clinically meaningful improvement in overall survival (OS) versus placebo. Specifically, median OS was 10.2 months with cabozantinib versus 8.0 months with placebo (HR 0.76, 95% CI 0.63-0.92; p=0.0049). Median progression-free survival (PFS) was more than doubled, at 5.2 months with cabozantinib and 1.9 months with placebo (HR 0.44, 95% CI 0.36-0.52; p<0.0001). Objective response rates per RECIST 1.1 were 4% with cabozantinib and 0.4% with placebo (p=0.0086). Disease control (partial response or stable disease) was achieved by 64% of patients in the cabozantinib group compared with 33% of patients in the placebo group.
Osphena™ (ospemifene) Tablets / Duchesnay Inc.	Endocrine-Metabolic agent; Selective Estrogen Receptor Modulator; Estrogen agonist/antagonist	**Previous indication(s):** To treat women experiencing moderate to severe dyspareunia (pain during sexual intercourse), a symptom of vulvar and vaginal atrophy (VVA) due to menopause **New indication:** To treat moderate to severe vaginal dryness, another symptom of VVA due to menopause	01/25/2019	Osphena™ is non-hormonal and helps improve specific vaginal tissues by increasing superficial cells, decreasing parabasal cells and reducing vaginal pH. This approval was based on new safety and efficacy data acquired through a confirmatory phase 3 randomized, double blind, placebo-controlled multicenter study evaluating the efficacy and safety of ospemifene in patients with moderate to severe vaginal dryness. Prior to this approval, Osphena™ was indicated only for the treatment of moderate to severe dyspareunia (painful intercourse), also a symptom of VVA, due to menopause.

New FDA Approved Dosage Forms, Formulations, and Other Differences

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Tosymra™ (sumatriptan) Nasal Spray / Dr. Reddy's Laboratories, Inc.	Antimigraine; Serotonin (5-HT1B/1D) receptor agonist (triptan)	Acute treatment of migraine with or without aura in adults	01/25/2019	Tosymra™ is an intranasal spray containing sumatriptan 10mg, a selective 5-HT1B/1D receptor agonist. The spray contains a permeation-enhancing excipient (Intravail), which allows the product to be quickly absorbed into the systemic circulation while demonstrating a similar pharmacokinetic profile as subcutaneous (SC) sumatriptan.
Evekeo ODT™ (amphetamine sulfate) / Arbor Pharms LLC	Central nervous system agent; Central nervous system stimulant; Amphetamine	Treatment of Attention Deficit Hyperactivity Disorder (ADHD) in pediatric patients 6 to 17 years of age.	01/30/2019	Evekeo ODT™ contains amphetamine sulfate in a new dosage form: orally disintegrating tablet. Evekeo™ was available as tablet (5 mg and 10 mg), which is also available in generic.
Gloperba™ (colchicine) / Romeg Therapeutics LLC	Antigout	For prophylaxis of gout flares in adults	01/30/2019	Gloperba™ contains colchicine in a new dosage form: oral solution. Colchicine was previously available as oral capsule and oral tablet. Both formulations were available in generic an under the brans Mitigare™ (oral capsule) and Colcrys (oral tablet).

New First Time Generic Drug Approval

Drug/Manufacturer	Therapeutic Class	Date	Comments
Lurasidone Hydrochloride Tablets 20 mg, 40 mg, 60 mg, 80 mg and 120 mg / Amneal Pharmaceuticals LLC; InvaGen Pharmaceuticals Inc.; Lupin Pharmaceuticals, Inc.; Accord Healthcare Inc.; Torrent Pharmaceuticals Limited	Central nervous system agent; Antipsychotic	01/03/2019	Generic for: Latuda
Ingenol Mebutate Topical Gel 0.015% / Perrigo	Dermatological agent	01/07/2019	Generic for: Picato Gel 0.015%
Ingenol Mebutate Topical Gel 0.05% / Perrigo	Dermatological agent	01/09/2019	Generic for: Picato Gel 0.05%
Vigabatrin Tablets 500 mg / Teva Pharmaceuticals USA, Inc.	Central nervous system agent; Anticonvulsant	01/14/2019	Generic for: Sabril
Wixela Inhub (fluticasone propionate and salmeterol inhalation powder) 100 mcg/50 mcg, 250 mcg/50 mcg and 500 mcg/50 mcg / Mylan N.V.	Antiasthma	01/30/2019	Generic for: Advair Diskus

Source: https://www.drugs.com/generic-approvals.html

PIPELINE……

Drug/Manufacturer	Date	Indications	Comments	Impact
Contepo (fosfomycin) / Nabriva Therapeutics plc	01/04/2019	Treatment for: Complicated urinary tract infections (cUTIs)	Contepo is an investigational epoxide antibiotic in development as a first-line treatment for cUTIs, including acute pyelonephritis. Nabriva Therapeutics announced the acceptance of the NDA for Contepo. If approved in the US, represents a first-in-class intravenous antibiotic with broad spectrum activity against Gram-negative and Gram-positive organisms, including ESBL-producing Enterobacteriaceae and other contemporary multi-drug resistant (MDR) organisms.	Moderate
Lemborexant / Eisai Co., Ltd.	01/15/2019	Treatment for: Insomnia	Lemborexant is dual orexin receptor antagonist (DORA) in development for the treatment of insomnia. An NDA has been submitted for lemborexant.	Moderate

Soruce: https://www.drugs.com/new-drug-applications.html

References:

- Drugs.com (www.drugs.com)
- Food and Drug Administration (www.fda.gov)
- IBM Micromedex® (www.micromedexsolutions.com)
- Pharmacist Letter (www.pharmacistletter.com)
- P&T Community (www.ptcommunity.com)