OPTUMRx®

RxHighlights

January 2022

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New drugs

Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Bijuva® (estradiol/progesterone) 0.5 mg/100 mg capsule TherapeuticsMD	Estrogen/ progesterone	Treatment of moderate to severe vasomotor symptoms due to menopause	TBD
Cibinqo® (abrocitinib)* Pfizer	Janus kinase 1 inhibitor	Treatment of adults with refractory, moderate-to-severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies is inadvisable	TBD
Dapzura RT (daptomycin) Baxter	Lipopeptide antibacterial	Treatment of adult and pediatric patients (1 to 17 years of age) with complicated skin and skin structure infections caused by susceptible isolates of certain Gram-positive bacteria; treatment of adult patients with *Staphylococcus aureus* bloodstream infections, including adult patients with right sided infective endocarditis, caused by methicillin-susceptible and methicillin-resistant isolates; treatment of pediatric patients (1 to 17 years of age) with *Staphylococcus aureus* bloodstream infections	TBD
Kimmtrak® (tebentafusp-tebn)†* Immunocore	Bispecific gp100 peptide-HLA-directed CD3 T cell engager	Treatment of HLA-A*02:01-positive adult patients with unresectable or metastatic uveal melanoma	January 30, 2022
Quviviq™ (daridorexant)* Idorsia	Orexin receptor antagonist	Treatment of adult patients with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance	May 2022

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Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Recorlev® (levoketoconazole)† Xeris Biopharma	Cortisol synthesis inhibitor	Treatment of endogenous hypercortisolemia in adult patients with Cushing's syndrome for whom surgery is not an option or has not been curative	First Quarter 2022
Ryaltris™ (olopatadine/mometasone furoate monohydrate) Glenmark	Corticosteroid/ antihistamine	Treatment of symptoms of seasonal allergic rhinitis in adult and pediatric patients 12 years of age and older	TBD
Spikevax™ (COVID-19 vaccine, mRNA) Moderna	Vaccine	Active immunization to prevent COVID-19 caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older	TBD
Tascenso ODT™ (fingolimod) 0.25 mg orally disintegrating tablet Handa Neuroscience	Sphingosine 1-phosphate receptor modulator	Treatment of relapsing forms of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in pediatric patients 10 years of age and older and weighing less than or equal to 40 kg	TBD
Vabysmo™ (faricimab-svoa)* Genentech	Bispecific VEGF-A/ angiopoietin-2 inhibitor	Treatment of patients with neovascular (wet) age-related macular degeneration and diabetic macular edema	February 1, 2022

*New molecular entity; † Orphan drug; TBD: To be determined

New generics

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Drug name Manufacturer(s)	Generic manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
Cuvposa® (glycopyrrolate) Merz Pharmaceuticals	Par†	1 mg/5 mL oral solution	To reduce chronic severe drooling in patients aged 3 to 16 years with neurologic conditions associated with problem drooling	January 4, 2022
Vasostrict® (vasopressin) Par	Eagle Pharmaceuticals†*	20 units/mL 200 units/10 mL, 20 units/100 mL, 40 units/100 mL, 60 units/100 mL injection	To increase blood pressure in adults with vasodilatory shock who remain hypotensive despite fluids and catecholamines	January 17, 2022

†A-rated generic manufacturer
*180-days of marketing exclusivity

New authorized brand alternatives

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Drug name Manufacturer(s)	Generic manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
Combigan® (brimonidine/timolol) Allergan	Apotex	0.2%/0.5% ophthalmic solution	For the reduction of elevated intraocular pressure (IOP) in patients with glaucoma or ocular hypertension who require adjunctive or replacement therapy due to inadequately controlled IOP	January 19, 2022

Indications/Label updates

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Drug name Manufacturer(s)	Type	Description
Bamlanivimab/etesevimab and **REGN-COV** (casirivimab/imdevimab) Eli Lilly, Regeneron	Emergency use authorization (EUA) revision	The FDA revised the EUAs for bamlanivimab/etesevimab and REGEN-COV, limiting their use to only when the patient is likely to have been infected with or exposed to a variant that is susceptible to these treatments.
COVID-19 Vaccine Moderna	Expanded EUA	The FDA announced expanded emergency use authorization for the Moderna COVID-19 vaccine, a single Moderna COVID-19 vaccine booster dose may be administered at least 5 months after completing a primary series of the Moderna COVID-19 vaccine to individuals 18 years of age or older.
COVID-19 Vaccine Pfizer/BioNTech	Expanded EUA	The FDA announced expanded emergency use authorization for the Pfizer/BioNTech COVID-19 vaccine, for the following: expand the use of a single booster dose to include use in individuals 12 through 15 years of age; shorten the time between the completion of primary vaccination of the Pfizer/BioNTech COVID-19 vaccine and a booster dose to at least five months in individuals 12 years and older; allow for a third primary series dose for certain immunocompromised children 5 through 11 years of age.
Descovy® (emtricitabine/tenofovir alafenamide) Gilead	Expanded indication, new strength	In combination with other antiretroviral agents other than protease inhibitors that require a CYP3A inhibitor, for the treatment of HIV-1 infection in pediatric patients weighing at least 14 kg and less than 35 kg The FDA approved a new tablet strength of Descovy, 120 mg of emtricitabine and 15 mg of enofovir alafenamide, to support the expanded indication.
Pifeltro™ (doravirine) and **Delstrigo**™ (doravirine/lamivudine/tenofovir disoproxil fumarate) Merck	Expanded indications	Treatment of HIV-1 infection in adults and pediatric patients weighing at least 35 kg with no prior antiretroviral treatment history; or to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies/mL) on a stable antiretroviral regimen with no history of treatment failure and no known substitutions associated with resistance to doravirine or to the individual components of Delstrigo
Rinvoq® (upadacitinib) AbbVie	New indication	Treatment of adults and pediatric patients 12 years of age and older with refractory, moderate to severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies are inadvisable

Drug name Manufacturer(s)	Type	Description
Skyrizi® (risankizumab-rzaa) AbbVie	New indication	Treatment of active psoriatic arthritis in adults
Solosec® (secnidazole) Lupin Pharmaceuticals	Expanded indication	Treatment of bacterial vaginosis in female patients 12 years of age and older and Trichomoniasis caused by *Trichomonas vaginalis* in patients 12 years of age and older
Veklury® (remdesivir) Gilead	Expanded indication	Treatment of COVID-19 in adults and pediatric patients (12 years of age and older and weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, who are not hospitalized and have mild-to-moderate COVID-19, and are at high risk for progression to severe COVID-19, including hospitalization or death
	EUA revision	Treatment of pediatric patients weighing 3.5 kilograms to less than 40 kilograms or pediatric patients less than 12 years of age weighing at least 3.5 kilograms, with positive results of direct SARS-CoV-2 viral testing, and who are not hospitalized and have mild-to-moderate COVID-19, and are at high risk for progression to severe COVID-19, including hospitalization of death. Previously the EUA allowed for treatment of this same group of patients who were hospitalized.
Vonvendi® (von Willebrand factor [recombinant]) Takeda	New indication	For use in adults (age 18 and older) diagnosed with von Willebrand disease for routine prophylaxis to reduce the frequency of bleeding episodes in patients with severe Type 3 VWD receiving on-demand therapy
Zydelig® (idelalisib) Gilead Sciences	Indication withdrawals	Gilead announced the voluntary withdrawal of Zydelig for the treatment of patients with relapsed follicular B-cell non-Hodgkin lymphoma who have received at least two prior systemic therapies and treatment of patients with relapsed small lymphocytic lymphoma who have received at least two prior systemic therapies

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Drug safety news / Drug updates

Drug name Manufacturer(s)	Description
Buprenorphine-containing transmucosal drugs	The FDA announced a warning that dental problems have been reported with medicines containing buprenorphine that are dissolved in the mouth. The dental problems, including tooth decay, cavities, oral infections, and loss of teeth, can be serious and have been reported even in patients with no history of dental issues.

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Drug recalls/Withdrawals/Shortages/Discontinuations

Drug name Manufacturer(s)	Strength(s) and dosage form(s)	Type	Description
Hizentra® [immune globulin subcutaneous (human)] CSL Behring	20% liquid, 50 mL vial containing 10 g of protein	Withdrawal	CSL Behring announced a patient-level withdrawal of several lots of Hizentra due to an increased frequency of reports of injection-site reactions and local hypersensitivity-type of events after administration. Hizentra is indicated for the treatment of primary immunodeficiency in adults and pediatric patients 2 years of age and older and for maintenance therapy in adults with chronic inflammatory demyelinating polyneuropathy.
Metformin Viona	750 mg extended-release tablets	Recall	Viona announced a consumer level recall of twenty-three lots of metformin 750 mg ER tablets due to the detection of N-nitrosodimethylamine levels above the acceptable daily intake limit in one lot. Metformin is indicated as an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients ≥ 10 years of age with type 2 diabetes mellitus.
Polymyxin B for injection AuroMedics	500,000 units/vial	Recall	The FDA announced a recall of one lot of polymyxin B for injection to the consumer level due to a product complaint for the presence of particulate matter, identified as hair being discovered in a vial.

Drug name Manufacturer(s)	Strength(s) and dosage form(s)	Type	Description
			Polymyxin B for injection is indicated in the treatment of infections or the urinary tract, meninges, and bloodstream caused by susceptible strains of bacteria.
RevitaDerm® (benzalkonium chloride) **Blaine Labs**	0.1% Gel	Recall	Blaine Labs announced a recall of one lot of RevitaDerm Wound Care gel to the consumer level because a 1.0 ounce bottle has been found to be contaminated with *Bacillus cereus*. RevitaDerm is an over-the-counter medication used to treat 1st and 2nd degree burns, stasis ulcers, pressure ulcers, diabetic ulcers, lacerations, abrasions, skin tears, surgical incision sites, device insertion sites, graft sites, and donor sites.
Semglee® (insulin glargine injection) Mylan	100 units/mL (U-100), 3 mL prefilled pen	Recall	The FDA announced a recall of one batch of non-interchangeable Semglee prefilled pens which are packaged in a labeled carton of five pens because of the potential for the label to be missing on some prefilled pens within a labelled carton for this batch. Semglee is indicated to improve glycemic control in adults and pediatric patients with type 1 diabetes mellitus and in adults with type 2 diabetes mellitus.
Senna syrup Lohxa	8.8 mg/5 mL unit dose cups	Recall	Lohxa announced a consumer level recall of one lot of senna syrup 8.8 mg/5 mL unit dose cups due to microbial contamination. Senna syrup is used to relieve occasional constipation.
Wegovy® (semaglutide) Novo Nordisk	0.25 mg/mL, 0.5 mg/mL and 1 mg/mL injection	Shortage	There is a supply disruption of Novo Nordisk's Wegovy 0.25 mg, 0.5 mg and 1 mg strengths until the 2nd half of 2022 due to manufacturing delays. The 1.7 mg and 2.4 mg dose strengths are expected to experience minimal disruption. Wegovy is indicated as an adjunct to a reduced calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index of 30 kg/m2 or greater or 27 kg/m2 in the presence of at least one weight-related comorbid condition [e.g. hypertension, type 2 diabetes mellitus (T2DM), or dyslipidemia].

Key guideline/Literature updates

Topic	Reference
National Institutes of Health – COVID-19 Treatment	*COVID-19 Treatment Guidelines*. February 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Acute Lymphoblastic Leukemia - Version 4.2021	*NCCN Clinical Practice Guidelines in Oncology: Acute Lymphoblastic Leukemia*. January 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma - Version 2.2022	*NCCN Clinical Practice Guidelines in Oncology: Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma*. January 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Chronic Myeloid Leukemia - Version 3.2022	*NCCN Clinical Practice Guidelines in Oncology: Chronic Myeloid Leukemia*. January 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Gastric Cancer - Version 2.2022	*NCCN Clinical Practice Guidelines in Oncology: Gastric Cancer*. January 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Gastrointestinal Stromal Tumors (GIST) - Version 1.2022	*NCCN Clinical Practice Guidelines in Oncology: Gastrointestinal Stromal Tumors (GIST)*. January 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Melanoma: Cutaneous - Version 2.2022	*NCCN Clinical Practice Guidelines in Oncology: Melanoma: Cutaneous*. January 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Myelodysplastic Syndromes - Version 3.2022	*NCCN Clinical Practice Guidelines in Oncology: Myelodysplastic Syndromes*. January 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer - Version 1.2022	*NCCN Clinical Practice Guidelines in Oncology: Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer*. January 2022

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Penile Cancer - Version 2.2022	*NCCN Clinical Practice Guidelines in Oncology: Penile Cancer*. January 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Primary Cutaneous Lymphomas - Version 1.2022	*NCCN Clinical Practice Guidelines in Oncology: Primary Cutaneous Lymphomas*. January 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Prostate Cancer - Version 3.2022	*NCCN Clinical Practice Guidelines in Oncology: Prostate Cancer*. January 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Soft Tissue Sarcoma - Version 3.2021	*NCCN Clinical Practice Guidelines in Oncology: Soft Tissue Sarcoma*. January 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Testicular Cancer - Version 2.2022	*NCCN Clinical Practice Guidelines in Oncology: Testicular Cancer*. January 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Breast Cancer Risk Reduction - Version 1.2022	*NCCN Clinical Practice Guidelines in Oncology: Breast Cancer Risk Reduction*. January 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Adult Cancer Pain - Version 1.2022	*NCCN Clinical Practice Guidelines in Oncology: Adult Cancer Pain*. January 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Antiemesis - Version 1.2022	*NCCN Clinical Practice Guidelines in Oncology: Antiemesis*. January 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Distress Management - Version 2.2022	*NCCN Clinical Practice Guidelines in Oncology: Distress Management*. January 2022

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