

New drugs

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Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Eysuvis™ (loteprednol etabonate) 0.25% ophthalmic suspension Kala Pharmaceuticals	Corticosteroid	Short-term (up to two weeks) treatment of the signs and symptoms of dry eye disease	Fourth quarter 2020
Inmazed™ (atoltivimab/maftivimab/ odesivimab-ebgn) ^{†*} Regeneron	Anti-Ebola virus	Treatment of infection caused by <i>Zaire ebolavirus</i> in adult and pediatric patients, including neonates born to a mother who is RT-PCR positive for <i>Zaire ebolavirus</i> infection	TBD
Sklice® (ivermectin) [±] Arbor Pharmaceuticals	Pediculicide	Treatment of head lice	TBD
Veklury® (remdesivir)* Gilead	Nucleotide analogue	For adults and pediatric patients (12 years of age and older and weighing at least 40 kg) for the treatment of coronavirus disease 2019 (COVID-19) requiring hospitalization	October 22, 2020

*New molecular entity; †Orphan Drug; ±New prescription to over-the-counter approval; 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
Atripla [®] (efavirenz/emtricitabine/tenofovir disoproxil fumarate) Gilead	Teva [†]	600 mg/200 mg/ 300 mg tablets	HIV-1 infection	October 2, 2020
Kerydin [®] (tavaborole) Pfizer	Encube Ethicals [†] , Perrigo ^{†^} , Alembic ^{†^}	5% topical solution	Onychomycosis of the toenails	October 15, 2020
Kuvan [®] (sapropterin) BioMarin	Par [†]	100 mg tablets and 100 mg and 500 mg powder for oral solution	Reduce blood phenylalanine levels in patients with hyperphenylalaninemia due to tetrahydrobiopterin-responsive phenylketonuria	October 1, 2020
Monurol [®] (fosfomycin) Allergan	Xiromed ^{†*}	3 gram oral solution	Uncomplicated urinary tract infections in women	October 6, 2020
Truvada [®] (emtricitabine/tenofovir disoproxil fumarate) Gilead	Teva [†]	200 mg/300 mg tablets	Human immunodeficiency virus (HIV)-1 infection; pre-exposure prophylaxis to reduce the risk of sexually acquired HIV- 1 infection	October 2, 2020

[†]A-rated generic manufacturer * Granted 180-days of exclusivity
[^]Perrigo received FDA approval October 13, 2020, launch pending; Alembic launched November 2, 2020

New authorized brand alternatives

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Drug name Manufacturer(s)	Generic manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
Kuvan [®] (sapropterin) BioMarin	Dr. Reddy's	100 mg tablets	Reduce blood phenylalanine levels in patients with hyperphenylalaninemia due to tetrahydrobiopterin-responsive phenylketonuria	October 3, 2020

Indications/label updates

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Drug name Manufacturer(s)	Type	Description
Keytruda [®] (pembrolizumab) Merck	Expanded indication	Treatment of adult patients with relapsed or refractory classical Hodgkin lymphoma (cHL) and for the treatment of pediatric patients with refractory cHL, or cHL that has relapsed after 2 or more lines of therapy
Opdivo [®] (nivolumab) and Yervoy [®] (ipilimumab) Bristol-Myers Squibb	New indication	Opdivo in combination with Yervoy, for the first-line treatment of adults with unresectable malignant pleural mesothelioma
Wakix [®] (pitolisant) Harmony Biosciences	Expanded indication	Treatment of cataplexy in adults with narcolepsy

Drug safety news

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Drug name Manufacturer(s)	Description
Nonsteroidal Anti-Inflammatory Drugs (NSAIDs)	The FDA announced the requirement of safety related changes to drug labels for both prescription and over-the-counter NSAIDs stating that use during pregnancy may cause rare but serious kidney problems in an unborn baby. Although this safety concern is well known among certain medical specialties, the FDA wants to communicate their recommendations more widely to educate other health care professionals and pregnant women.

Drug recalls/withdrawals/shortages/discontinuations

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Drug name Manufacturer(s)	Dosage form(s)	Type	Description
Metformin extended-release (ER) Marksans Pharma	500 mg, 750 mg ER tablets	Recall	Marksans announced a voluntary, consumer-level recall of an additional 76 lots of metformin extended release tablets due to the level of N-Nitrosodimethylamine (NDMA), which has been found to be above the allowable Acceptable Daily Intake limit established by the FDA. This is an expansion to the recall that was announced in June 2020. Metformin is indicated for the treatment of type 2 diabetes.
Paroex® (chlorhexidine gluconate) Sunstar Americas	0.12% oral rinse	Recall	The FDA announced a voluntary, consumer level recall of Paroex 0.12% oral rinse, labeled with expiration dates of 6/30/22 – 9/20/22, due to contamination with <i>Burkholderia lata</i> . Paroex is indicated for use between dental visits as part of a professional program for the treatment of gingivitis.

Key guideline/literature updates

Topic	Reference
American Burn Association - Management of Acute Pain in the Adult Burn Patient	<i>Journal of Burn Care & Research</i> . September 2020
American Diabetes Association - Pharmacologic Approaches to Glycemic Treatment of Type 2 Diabetes	<i>Annals of Internal Medicine</i> . September 2020
American Society of Clinical Oncology - Metastatic Pancreatic Cancer	<i>Journal of Clinical Oncology</i> . August 2020
American Psychiatric Association Practice – Treatment of Patients with Schizophrenia	<i>American Journal of Psychiatry</i> . September 2020.
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Acute Lymphoblastic Leukemia - Version 2.2020	<i>NCCN Clinical Practice Guidelines in Oncology: Acute Lymphoblastic Leukemia</i> . October 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Acute Myeloid Leukemia - Version 1.2021	<i>NCCN Clinical Practice Guidelines in Oncology: Acute Myeloid Leukemia</i> . October 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Cervical Cancer - Version 1.2021	<i>NCCN Clinical Practice Guidelines in Oncology: Cervical Cancer</i> . October 2020

National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Gastrointestinal Stromal Tumors (GIST) - Version 1.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Gastrointestinal Stromal Tumors (GIST).</u> October 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Gestational Trophoblastic Neoplasia - Version 3.2020	<u>NCCN Clinical Practice Guidelines in Oncology: Gestational Trophoblastic Neoplasia.</u> October 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Malignant Pleural Mesothelioma - Version 2.2020	<u>NCCN Clinical Practice Guidelines in Oncology: Malignant Pleural Mesothelioma.</u> October 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Multiple Myeloma - Version 3.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Multiple Myeloma.</u> October 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Pancreatic Adenocarcinoma - Version 1.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Pancreatic Adenocarcinoma.</u> October 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Pediatric Acute Lymphoblastic Leukemia - Version 2.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Pediatric Acute Lymphoblastic Leukemia.</u> October 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Pediatric Hodgkin Lymphoma – Version 2.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Pediatric Hodgkin Lymphoma.</u> October 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Primary Cutaneous Lymphomas - Version 1.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Primary Cutaneous Lymphomas.</u> October 2020

National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Soft Tissue Sarcoma - Version 1.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Soft Tissue Sarcoma.</u> October 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: T-Cell Lymphomas - Version 1.2021	<u>NCCN Clinical Practice Guidelines in Oncology: T-Cell Lymphomas.</u> October 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Uterine Neoplasms - Version 1.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Uterine Neoplasms.</u> October 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Vulvar Cancer - Version 2.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Vulvar Cancer.</u> October 2020



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