

RxHighlights

November 2024

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New drugs

Drug name manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Aucatzyl [®] (obecabtagene autoleucl) [†] Autolus	Chimeric antigen receptor T cell	Treatment of adults with relapsed or refractory B-cell precursor acute lymphoblastic leukemia.	November 8, 2024
Attruby [™] (acoramidis) ^{†*} BridgeBio Pharma	Transthyretin stabilizer	Treatment of the cardiomyopathy of wild-type or variant transthyretin-mediated amyloidosis (ATTR-CM) in adults to reduce cardiovascular death and cardiovascular-related hospitalization.	November 22, 2024
Danziten (nilotinib) Azurity Pharmaceuticals	Kinase inhibitor	Treatment of adult patients with: (1) newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase; and (2) chronic phase and accelerated phase Ph+ CML resistant or intolerant to prior therapy that included imatinib	November 7, 2024
Emrosi [™] (minocycline) Journey Medical	Tetracycline	Treatment of inflammatory lesions (papules and pustules) of rosacea in adults.	November 4, 2024
Imkeldi (imatinib) Shorla	Kinase inhibitor	Treatment of: (1) newly diagnosed Philadelphia positive chronic myeloid leukemia (Ph+ CML); (2) Ph+ CML in blast crisis, accelerated phase or chronic phase after interferon-alpha therapy; (3) adult patients with Ph+ acute lymphoblastic leukemia (ALL); (4) pediatric patients With Ph+ ALL; (5) myelodysplastic/myeloproliferative diseases;	November 22, 2024

Drug name manufacturer(s)	Therapeutic category	Indication(s)	Launch information
		(6) aggressive systemic mastocytosis; (7) hypereosinophilic syndrome and/or chronic eosinophilic leukemia; (8) dermatofibrosarcoma protuberans; Kit+ gastrointestinal stromal tumors (GIST); and (9) adjuvant treatment of GIST	
Kebilidi (eladocagene exuparvovec-tneq) [†] PTC Therapeutics	Gene therapy	Treatment of adult and pediatric patients with aromatic L-amino acid decarboxylase (AADC) deficiency.	November 14, 2024
Rapiblyk (landiolol)* AOP Orphan Pharmaceuticals	Beta adrenergic blocker	For the short-term reduction of ventricular rate in adults with supraventricular tachycardia including atrial fibrillation and atrial flutter.	November 22, 2024
Revuforj [®] (revumenib) [†] Syndax	Menin inhibitor	Treatment of relapsed or refractory acute leukemia with a lysine methyltransferase 2A gene (KMT2A) translocation in adult and pediatric patients 1 year and older.	November 15, 2024
Ziihera [®] (zanidatamab-hrii) [†] Jazz Pharmaceuticals	HER2 monoclonal antibody	Treatment of adults with previously treated, unresectable or metastatic HER2-positive (IHC 3+) biliary tract cancer, as detected by an FDA-approved test.	November 20, 2024

* New molecular entity; †Orphan drug

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Indications/Label updates

Drug name manufacturer(s)	Type	Description
Bimzelx [®] (bimekizumab-bkzx) UCB	New Indication	Treatment of adults with moderate to severe hidradenitis suppurativa.

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Drug safety news / Drug updates

Drug name manufacturer(s)	Description
<p>Skysona™ (elivaldogene autotemcel)</p>	<p>The FDA announced it is investigating reports of hematologic malignancies associated with the use of Skysona (elivaldogene autotemcel).</p> <p>The FDA has received reports of hematologic malignancies, including life-threatening cases of myelodysplastic syndrome and acute myeloid leukemia, following treatment of early, active cerebral adrenoleukodystrophy (CALD) patients with Skysona.</p>

Drug recalls/Withdrawals/Shortages/Discontinuations

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Drug name manufacturer(s)	Strength(s) and dosage form(s)	Type	Description
<p>Radicava® (edaravone) Mitsubishi Tanabe</p>	<p>60 mg; 105 mg (5 mL) intravenous</p>	<p>Discontinuation</p>	<p>Mitsubishi Tanabe announced a business decision to discontinue intravenous (IV) Radicava (edaravone). Radicava IV is not being discontinued for reasons of safety or effectiveness.</p>
<p>clonazepam Endo</p>	<p>0.125mg; 0.25 mg; 1 mg & 2 mg orally disintegrating tablets</p>	<p>Recall</p>	<p>Endo announced a voluntary, consumer level recall of many lots of clonazepam ODT tablets because of potential product carton strength mislabeling. The recall was first announced on July 5, 2024.</p>

Key guideline/Literature updates from the National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology – November 2024

- Anal Carcinoma Version 1.2025
- Biliary Tract Cancers Version 5.2024
- Breast Cancer Version 6.2024
- Chronic Myeloid Leukemia Version 3.2025
- Head and Neck Cancers Version 1.2025
- Mesothelioma: Peritoneal Version 1.2025
- Mesothelioma: Pleural Version 1.2025
- Myelodysplastic Syndromes Version 1.2025
- Pediatric Central Nervous System Cancers Version 1.2025
- Primary Cutaneous Lymphomas Version 1.2025
- Prostate Cancer Version 1.2025
- Small Bowel Adenocarcinoma Version 1.2025
- Genetic/Familial High-Risk Assessment: Breast, Ovarian, Pancreatic, and Prostate Version 2.2025
- T-Cell Lymphomas Version 1.2025
- Adult Cancer Pain Version 3.2024
- Cancer-Related Fatigue Version 1.2025
- Distress Management Version 1.2025
- Palliative Care Version 1.2025
- Smoking Cessation Version 2.2024
- Hematopoietic Growth Factors Version 1.2025

Reference: <https://www.nccn.org/guidelines/recently-published-guidelines>



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