

# RxHighlights

December 2023

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## New drugs

Drug name manufacturer(s)	Therapeutic category	Indication(s)	Launch information
<b>Alyglo™</b> (immune globulin intravenous, human-stwk) GC Biopharma	Immunoglobulin	Treatment of primary humoral immunodeficiency in adults	TBD
<b>Casgevy™</b> (exagamglogene autotemcel)† Vertex	Autologous genome edited hematopoietic stem cell-based gene therapy	Treatment of sickle cell disease in patients 12 years and older with recurrent vaso-occlusive crises	December 14, 2023
<b>Fabhalta®</b> (iptacopan)†* Novartis	Factor B inhibitor	Treatment of adults with paroxysmal nocturnal hemoglobinuria	December 08, 2023
<b>Filsuvez®</b> (birch triterpenes)†* Chiesi Global Rare Diseases	Triterpene	Treatment of wounds associated with dystrophic and junctional epidermolysis bullosa in adult and pediatric patients 6 months of age and older	TBD
<b>iDose® TR</b> (travoprost intracameral implant) Glaukos	Prostaglandin analog	To reduce intraocular pressure in patients with open-angle glaucoma or ocular hypertension	December 18, 2023
<b>Iwilfin™</b> (eflornithine)†* US WorldMeds	Irreversible inhibitor of ornithine decarboxylase	To reduce the risk of relapse in adult and pediatric patients with high-risk neuroblastoma who have demonstrated at least a partial response	December 21, 2023

Drug name manufacturer(s)	Therapeutic category	Indication(s)	Launch information
		to prior multiagent, multimodality therapy including anti-GD2 immunotherapy	
<b>Lyfgenia</b> <sup>®</sup> (lovotibeglogene autotemcel) <sup>†</sup>  bluebird bio	Autologous hematopoietic stem cell-based gene therapy	Treatment of sickle cell disease in patients 12 years and older with a history of vaso-occlusive events	December 14, 2023
<b>Wainua</b> <sup>™</sup> (eplontersen) <sup>†*</sup>  AstraZeneca and Ionis	Antisense oligonucleotide	Treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults	December 27, 2023
<b>Zoryve</b> <sup>®</sup> (roflumilast) 0.3% foam  Arcutis Biotherapeutics	Phosphodiesterase-4 inhibitor	Treatment of seborrheic dermatitis in adult and pediatric patients 9 years of age and older	December 20, 2023

\*New molecular entity; <sup>†</sup>Orphan drug; TBD: To be determined

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## New biosimilars

Drug name manufacturer(s)	Therapeutic category	Indication(s)	Launch information
<b>Avzivi</b> <sup>®</sup> (bevacizumab-tjnj) Bio-Thera/Sandoz	Vascular endothelial growth factor	Treatment of metastatic colorectal cancer; First-line non-squamous non–small cell lung cancer; Recurrent glioblastoma; Metastatic renal cell carcinoma; Persistent, recurrent, or metastatic cervical cancer, and Epithelial ovarian, fallopian tube, or primary peritoneal cancer	TBD
<b>Udenyca</b> <sup>®</sup> <b>Onbody</b> <sup>™</sup> (pegfilgrastim-cbqv) Coherus	Granulocyte colony- stimulating factor	To decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia	First quarter of 2024

TBD: To be determined

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## New generics

Drug name manufacturer(s)	Generic manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
<b>Condylox</b> <sup>®</sup> (podofilox) AbbVie	Padagis <sup>† §</sup>	0.5% gel	Topical treatment of anogenital warts	December 7, 2023
<b>Nascobal</b> (cyanocobalamin) Par	Lupin <sup>†</sup> , Padagis/Perrigo <sup>†</sup>	500 mcg/0.1 mL nasal spray	Treatment and prevention of vitamin B12 deficiency	December 28, 2023
<b>ProvayBlue</b> <sup>®</sup> (methylene blue) Provepharm/American Regent	Zydus <sup>†</sup>	10 mg/2 mL and 50 mg/10 mL vials	Treatment of acquired methemoglobinemia	December 7, 2023

Drug name manufacturer(s)	Generic manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
<b>Risperdal Consta<sup>®</sup></b> (risperidone) Janssen	Teva <sup>†</sup>	12.5 mg, 25 mg, 37.5 mg, and 50 mg vials	Treatment of schizophrenia and Bipolar I Disorder	December 12, 2023

<sup>†</sup>A-rated generic manufacturer  
<sup>§</sup>180-day market exclusivity

## Indications/Label updates

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Drug name manufacturer(s)	Type	Description
<b>Adbry<sup>®</sup></b> (tralokinumab-ldrm) Leo Pharma	Expanded indication	Treatment of moderate-to-severe atopic dermatitis in patients aged 12 years and older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.
<b>Bivigam<sup>®</sup></b> (immune globulin intravenous [human]) ADMA Biologics	Expanded indication	Treatment of adults and pediatric patients 2 years of age and older with primary humoral immunodeficiency
<b>Cresemba<sup>®</sup></b> (isavuconazonium) Astellas	Expanded indication	Treatment of invasive aspergillosis and invasive mucormycosis in pediatric patients
<b>Jaypirca<sup>®</sup></b> (pirtobrutinib) Eli Lilly	New indication	Treatment of adult patients with chronic lymphocytic leukemia or small lymphocytic lymphoma who have received at least two prior lines of therapy, including a BTK inhibitor and a BCL-2 inhibitor
<b>Keytruda<sup>®</sup></b> (pembrolizumab) plus <b>Padcev<sup>®</sup></b> (enfortumab vedotin-ejfv) Astellas/Pfizer, Merck	Expanded indication, accelerated approval converted to full approval	Treatment of adult patients with locally advanced or metastatic urothelial cancer
<b>Tarpeyo<sup>®</sup></b> (budesonide) Calliditas Therapeutics	Updated indication; Accelerated	To reduce the loss of kidney function in adults with primary immunoglobulin A nephropathy who are at risk for disease progression <sup>a</sup>

Drug name manufacturer(s)	Type	Description
	approval converted to full approval	
<b>Welireg®</b> (belzutifan) Merck	New indication	Treatment of adult patients with advanced renal cell carcinoma following a programmed death receptor-1 or programmed death-ligand 1 inhibitor and a vascular endothelial growth factor tyrosine kinase inhibitor
<b>Wilate</b> (von Willebrand factor/coagulation factor VIII complex [human]) Octapharma	Expanded indication	In children and adults with von Willebrand disease for routine prophylaxis to reduce the frequency of bleeding episodes

### Drug safety news / Drug updates

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Drug name manufacturer(s)	Description
<b>Carvykti®</b> (ciltacabtagene autoleucel) Janssen	The FDA approved a new <i>Boxed Warning</i> to Carvykti regarding secondary hematological malignancies.

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### Drug recalls/Withdrawals/Shortages/Discontinuations

Drug name manufacturer(s)	Strength(s) and dosage form(s)	Type	Description
<b>Americaine®</b> (benzocaine) Insight	20% topical anesthetic spray	Recall	Insight announced a consumer level recall of one lot of Americaine because a third-party lab found that a sample of this lot showed a low level of benzene came from the propellant that sprays the product out of the can. Benzene is not an ingredient in any Americaine products.

Drug name manufacturer(s)	Strength(s) and dosage form(s)	Type	Description
			Americaine is used to temporarily relieve pain and itching associated with minor cuts, scrapes, minor burns and insect bites.
<b>Atropine</b> Hospira	1 mg/10 mL injection	Recall	Hospira recalled one lot of atropine injection because of the potential for the presence of glass particulate matter.  Atropine is indicated for temporary blockade of severe or life-threatening muscarinic effects, an antidote for organophosphorus or muscarinic mushroom poisoning, and to treat bradycardiac arrest.
<b>Attention Deficit Hyperactivity Disorder (ADHD) Medication Class</b>	Various	Shortage	There is currently a nationwide shortage of generic Adderall® XR (amphetamine-dextroamphetamine ER) and generic Adderall® IR (amphetamine-dextroamphetamine) products, generic Vyvanse® (lisdexamfetamine) capsules and chewable tablets, and generic Concerta® (methylphenidate) used to treat ADHD, and the shortage may continue into 2024.
<b>Bleomycin</b> Hospira	15 units single-dose ONCO-TAIN™ glass flip-top vial injection	Recall	Hospira announced a consumer level recall of one lot of bleomycin due to a confirmed customer report for the presence of glass particulate within a single vial.  Bleomycin should be considered a palliative treatment useful in the management of neoplasms either as a single agent or in proven combinations with other approved chemotherapeutic agents.
<b>Levemir®</b> (insulin detemir) Novo Nordisk	100 units/mL (U-100) injection	Discontinuation	Novo Nordisk recently announced the discontinuation of Levemir due to business reasons. The discontinuation is not due to any safety or efficacy issues.  Levemir is indicated to improve glycemic control in adult and pediatric patients with diabetes mellitus.
<b>Nutramigen™ Powder</b> Reckitt/Mead Johnson	12.6 oz. and 19.8 oz cans	Recall	Reckitt/Mead Johnson announced a consumer level recall of select batches of Nutramigen Powder, a specialty infant formula for the dietary management of cows milk allergy, due to a possibility of contamination with <i>Cronobacter sakazakii</i> in product sampled outside the U.S.

Drug name manufacturer(s)	Strength(s) and dosage form(s)	Type	Description
<b>Sodium bicarbonate</b> Hospira	4.2%, 8.4% injection	Recall	Hospira recalled some lots of sodium bicarbonate injection products because of the potential for the presence of glass particulate matter. Sodium bicarbonate injection is indicated in the treatment of metabolic acidosis, certain drug intoxications, and severe diarrhea.
<b>Vigabatrin</b> InvaGen Pharmaceuticals	500 mg/sachet	Recall	InvaGen Pharmaceuticals announced a consumer level recall of one lot of vigabatrin oral solution because of seal integrity issues allowing for powder leakage from the pouch. Vigabatrin is indicated for the treatment of refractory complex partial seizures.

### Key guideline/Literature updates

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Ampullary Adenocarcinoma - Version 1.2024	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Ampullary Adenocarcinoma.</u></a> December 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Anal Carcinoma - Version 1.2024	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Anal Carcinoma.</u></a> December 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Breast Cancer - Version 5.2023	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Breast Cancer.</u></a> December 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Chronic Myeloid Leukemia - Version 2.2024	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Chronic Myeloid Leukemia.</u></a> December 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Head and Neck Cancers - Version 2.2024	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Head and Neck Cancers.</u></a>

Topic	Reference
	December 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusions - Version 1.2024	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusions.</u></a> December 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Myeloproliferative Neoplasms - Version 1.2024	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Myeloproliferative Neoplasms.</u></a> December 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer - Version 1.2024	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer.</u></a> December 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Pancreatic Adenocarcinoma - Version 1.2024	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Pancreatic Adenocarcinoma.</u></a> December 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Primary Cutaneous Lymphomas - Version 1.2024	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Primary Cutaneous Lymphomas.</u></a> December 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Small Bowel Adenocarcinoma - Version 1.2024	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Small Bowel Adenocarcinoma.</u></a> December 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Soft Tissue Sarcoma - Version 3.2023	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Soft Tissue Sarcoma.</u></a> December 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Systemic Light Chain Amyloidosis - Version 2.2024	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Systemic Light Chain Amyloidosis.</u></a> December 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Systemic Mastocytosis - Version 1.2024	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Systemic Mastocytosis.</u></a>

Topic	Reference
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National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: T-Cell Lymphomas - Version 1.2024	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: T-Cell Lymphomas.</u></a> December 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Vulvar Cancer - Version 3.2024	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Vulvar Cancer.</u></a> December 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Waldenström Macroglobulinemia / Lymphoplasmacytic Lymphoma - Version 2.2024	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Waldenström Macroglobulinemia / Lymphoplasmacytic Lymphoma.</u></a> December 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Prostate Cancer Early Detection - Version 1.2024	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Prostate Cancer Early Detection.</u></a> December 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Antiemesis - Version 1.2024	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Antiemesis.</u></a> December 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hematopoietic Growth Factors - Version 2.2024	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Hematopoietic Growth Factors.</u></a> December 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Management of Immunotherapy-Related Toxicities - Version 1.2024	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Management of Immunotherapy-Related Toxicities.</u></a> December 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Prevention and Treatment of Cancer-Related Infections - Version 2.2023	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Prevention and Treatment of Cancer-Related Infections.</u></a> December 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Older Adult Oncology - Version 1.2024	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Older Adult Oncology.</u></a> December 2023



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