Today, we are CarelonRx, but when we created this document, we were IngenioRx.

Our name may be new, but our commitment to you remains the same.

DrugInsights

Q4 2022

IngenioRx's *DrugInsights* provides a quarterly summary of Food and Drug Administration (FDA)-approved new molecular entities, formulations, and indications. We continue to closely monitor the FDA landscape to help provide our audiences with an understanding of the current drug and biologic market.

New molecular entities

Brand (generic)	Therapeutic class	Competitors	Indication(s)	Dosage	Manufacturer	Estimated wholesale acquisition cost (WAC)
Elahere™ (mirvetuximab soravtansine-gynx)	Folate receptor alpha (FRa)-directed antibody and microtubule inhibitor conjugate	First in class	Treatment of adults with FRa-positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who received one to three prior treatments	6 mg/kg adjusted ideal body weight administered as an intravenous infusion every 3 weeks until progression or toxicity	ImmunoGen	$19K to $25K each cycle
Lytgobi® (futibatinib)	Kinase inhibitor of fibroblast growth factor receptor (FGFR)	Pemazyre®, Truseltiq®	Treatment of adults with previously treated unresectable, locally advanced, or metastatic intrahepatic cholangiocarcinoma with FGFR2 gene fusions or other rearrangements	20 mg orally (five 4 mg tablets) once a day until progression or toxicity	Taiho Oncology	$23K each month

DISCLAIMER: Unless otherwise noted, information in this document was obtained from the FDA (fda.gov) and releases from pharmaceutical manufacturers and is accurate as of November 28, 2022.

New molecular entities (continued)

Brand (generic)	Therapeutic class	Competitors	Indication(s)	Dosage	Manufacturer	Estimated wholesale acquisition cost (WAC)
Imjudo® (tremelimumab-actl)	T-lymphocyte-associated antigen 4 (CTLA-4) blocking antibody	Nexavar®, Avastin® plus Tecentriq®	Treatment of adults with unresectable hepatocellular carcinoma (uHCC) in combination with Imfinzi® (durvalumab)	**Weight ≥ 30 kg:** Imjudo 300 mg single intravenous (IV) dose in combination with Imfinzi on cycle 1/day 1, followed by Imfinzi as single agent every 4 weeks **Weight < 30 kg:** Imjudo 4 mg/kg single IV dose in combination with Imfinzi on cycle 1/day 1, followed by Imfinzi as single agent every 4 weeks	AstraZeneca	$39K each single dose
Omlonti® (omidenepag isopropyl)	Prostaglandin E2 (EP2) receptor agonist	latanoprost, timolol	Reduction of elevated intraocular pressure (IOP) in people with open-angle glaucoma or ocular hypertension	One drop in the affected eye(s) once a day in the evening	Santen	Not available
Relyvrio™ (sodium phenylbutyrate/ taurursodiol)	Endocrine/ metabolic agent	Radicava®, riluzole	Treatment of adults with amyotrophic lateral sclerosis (ALS)	One packet added to one cup of room-temperature water by mouth or by feeding tube once a day for 3 weeks. Then 1 packet twice a day.	Amylyx	$158K each year

New molecular entities (continued)

Brand (generic)	Therapeutic class	Competitors	Indication(s)	Dosage	Manufacturer	Estimated wholesale acquisition cost (WAC)
Skysona® (elivaldogene autotemcel)	Gene therapy	First approval for this indication	To slow the progression of neurologic dysfunction in boys age 4 to 17 years with early, active cerebral adrenoleukodystrophy (CALD)	Dose is created using individual's own bone marrow cells that are genetically modified and then re-administered	bluebird bio	$3M for each one--time treatment
Sotyktu® (deucravacitinib)	Tyrosine kinase 2 (TYK2) inhibitor	Otezla®	Treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy	Dosage is 6 mg by mouth once a day	Bristol Myers Squibb	$75K each year
Spevigo® (spesolimab-sbzo)	Interleukin-36 (IL-36) receptor antagonist	First agent approved for this indication	Treatment of generalized pustular psoriasis flares in adults	Single 900 mg dose by intravenous infusion over 90 minutes. If symptoms persist, may give additional dose one week later.	Boehringer Ingelheim	$50K for each injection
Tzield™ (teplizumab-mzwv)	CD3-directed antibody	First FDA-approved agent for this indication	Delay the onset of Stage 3 type 1 diabetes (T1D) in adults and children age 8 years and older with Stage 2 T1D	Administer by intravenous infusion once a day for 14 days	Provention Bio	$193K for each 14--day course

New molecular entities (continued)

Brand (generic)	Therapeutic class	Competitors	Indication(s)	Dosage	Manufacturer	Estimated wholesale acquisition cost (WAC)
Xenpozyme™ (olipudase alfa-rpcp)	Hydrolytic lysosomal sphingomyelin-specific enzyme replacement therapy	First agent approved for this indication	Treatment of non–central nervous system (CNS) manifestations of acid sphingomyelinase deficiency (ASMD) in adults and children	Given by intravenous infusion every 2 weeks. Dosage based on body weight. Escalation regimen in labeling.	Genzyme	$7,142 for each vial

New formulations

Brand (generic)	Description
Aponvie™ (aprepitant)*	Aprepitant injectable emulsion approved for prevention of postoperative nausea and vomiting in adults.
Daxxify™ (daxibotulinumtoxinA-lanm)*	DaxibotulinumtoxinA-lanm approved for temporary improvement of moderate-to-severe frown lines (glabellar lines) in adults.
Furoscix® (furosemide)*	Furosemide delivered by an on-body infusor approved for treatment of congestion due to fluid overload in adults with NYHA Class II/III chronic heart failure.
Konvomep™ (omeprazole/sodium bicarbonate)	Omeprazole/sodium bicarbonate oral suspension approved for short-term treatment (4 to 8 weeks) of active benign gastric ulcer and reduction of risk of upper gastrointestinal bleeding in critically ill adults.
Pedmark® (sodium thiosulfate)*	Sodium thiosulfate injection approved for reduction of ototoxicity risk associated with cisplatin in people age1 month and older with localized, non-metastatic solid tumors.
Rolvedon™ (eflapegrastim-xnst)*	Eflapegrastim-xnst injection approved to decrease incidence of infection, as manifested by febrile neutropenia, in adults with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with clinically significant incidence of febrile neutropenia.
Rotarix® (rotavirus vaccine)	Rotavirus live oral vaccine approved as a liquid formulation that does not require reconstitution for prevention of gastroenteritis caused by G1 and non-G1 types (G3, G4, and G9) in infants.
Sezaby™ (phenobarbital sodium)*	Phenobarbital sodium powder for injection approved for treatment of neonatal seizures.
Terlivaz® (terlipressin)*	Synthetic analogue of vasopressin approved to improve kidney function in adults with hepatorenal syndrome with rapid reduction in kidney function.

* Injectable

New indications

Brand (generic)	Description
Adcetris® (brentuximab vedotin)*	Adcetris approved in combination with doxorubicin, vincristine, etoposide, prednisone, and cyclophosphamide for children age 2 years and older with previously untreated high-risk classical Hodgkin lymphoma (cHL).
Boostrix® (tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine, adsorbed)*	Boostrix approved for immunization expansion during the third trimester of pregnancy to prevent pertussis in babies younger than age 2 months.
Cotellic® (cobimetinib)	Cotellic approved for treatment of adults with histiocytic neoplasms.
Dupixent® (dupilumab)*	Dupixent approved for treatment of adults with prurigo nodularis.
Dupixent® (dupilumab)*	Dupixent single-use prefilled pen expanded to include use in children age 2 years and older for approved indications.
Firdapse® (amifampridine)	Firdapse approved to expand the indicated age range to include children age 6 years and older for treatment of Lambert-Eaton myasthenic syndrome (LEMS).
Imfinzi® (durvalumab)*	Imfinzi approved in combination with gemcitabine and cisplatin for adults with locally advanced or metastatic biliary tract cancer (BTC).
Libtayo® (cemiplimab-rwlc)*	Libtayo approved in combination with platinum-based chemotherapy for adults with advanced non-small cell lung cancer (NSCLC) with no epidermal growth factor receptor (EGFR), anaplastic lymphoma kinase (ALK), or ROS1 aberrations.
Liletta® (levonorgestrel)	Liletta approved for the prevention of pregnancy for up to 8 years.
Lyumjev™ (insulin lispro-aabc)*	Lyumjev approval expanded to improve glycemic control in children with diabetes mellitus.
Orkambi® (ivacaftor/ lumacaftor)	Orkambi approved to include treatment of cystic fibrosis (CF) in babies age 1 to less than 2 years who are homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene. A new strength of oral granules was also approved.
Oxlumo® (lumasiran)*	Oxlumo approved expanded label to include treatment of people with advanced primary hyperoxaluria type 1 (PH1).
Pemazyre® (pemigatinib)	Pemazyre approved for treatment of adults with relapsed or refractory myeloid/lymphoid neoplasms or MLNs with fibroblast growth factor receptor 1 (FGFR1) rearrangement.

New indications (continued)

Brand (generic)	Description
Retevmo® (selpercatinib)	Retevmo approved for adults with locally advanced or metastatic solid tumors with a rearranged during transfection (RET) gene fusion.
Rinvoq® (upadacitinib)	Rinvoq approved for the treatment of adults with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation who have had an inadequate response or intolerance to tumor necrosis factor (TNF) blocker therapy.
Trulicity® (dulaglutide)*	Trulicity approved as an adjunct to diet and exercise to improve glycemic control in children age 10 years and older with type 2 diabetes mellitus.
Vemlidy® (tenofovir alafenamide fumarate)	Vemlidy approved expanded label to include treatment of chronic hepatitis B virus infection in children age 12 years and older.

* Injectable