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

Q1 2021

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 WAC*
Breyanzi (lisocabtagene maraleucel)	Chimeric antigen receptor (CAR) T-cell therapy	Kymriah; Yescarta	Treatment of adults with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy	A single dose of 50 to 110 x 10^6 CAR-positive viable T cells (consisting of 1:1 CAR-positive viable T-cells of the CD8 and CD4 components) administered intravenously	Bristol-Myers Squibb	$410K per single treatment

*WAC = wholesale acquisition cost

New Molecular Entities, continued

Brand (Generic)	Therapeutic Class	Competitors	Indication(s)	Dosage	Manufacturer	Estimated WAC*
Cabenuva (cabotegravir/ rilpivirine)	Integrase strand transfer inhibitor (INSTI), non-nucleoside reverse transcriptase inhibitor (NNRTI)	Dovato, Juluca	Complete regimen for the treatment of human immunodeficiency virus (HIV)-1 infection in adults to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine	Initiate intramuscular (IM) gluteal injections of Cabenuva (600 mg of cabotegravir and 900 mg of rilpivirine) on the last day of oral lead-in and continue with injections of Cabenuva (400 mg of cabotegravir and 600 mg of rilpivirine) every month thereafter	ViiV Healthcare	$3,960 per month
Cosela (trilaciclib)	Cyclin-dependent kinase (CDK) 4/6 inhibitor	Granulocyte colony-stimulating factors; Erythropoiesis stimulating agents	Reduction of incidence of chemotherapy-induced myelosuppression in adults when administered prior to platinum/etoposide-containing regimen or topotecan-containing regimen for extensive-stage small cell lung cancer	Recommended dose is 240 mg/m^2 as a 30-minute intravenous infusion completed within 4 hours prior to the start of chemotherapy on each day chemotherapy is administered	G1 Therapeutics	Not available

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New Molecular Entities, continued

Brand (Generic)	Therapeutic Class	Competitors	Indication(s)	Dosage	Manufacturer	Estimated WAC*
Ebanga (ansuvimab-zykl)	Human IgG1 monoclonal antibody	Inmazeb	Treatment for *Zaire ebolavirus* infection	Single intravenous dose	Ridgeback Biotherapeutics	Not available
Evkeeza (evinacumab-dgnb)	Angiopoietin-like protein 3 (ANGPTL3) inhibitor monoclonal antibody	Ezetimibe; Repatha	As an adjunct to other low-density lipoprotein-cholesterol (LDL-C) lowering therapies for the treatment of adult and pediatric individuals, aged 12 years and older, with homozygous familial hypercholesterolemia (HoFH)	15 mg/kg per intravenous infusion every 4 weeks	Regeneron	$450K per year
Gemtesa (vibegron)	Beta-3 adrenergic agonist	Myrbetriq, oxybutynin, tolterodine	Treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency in adults	75 mg orally once daily	Urovant Sciences	$460 per month
Lupkynis (voclosporin)	Calcineurin-inhibitor immuno-suppressant	Benlysta	In combination with a background immunosuppressive therapy regimen for the treatment of adults with active lupus nephritis	Starting dose is 3 capsules taken orally twice daily	Aurinia	$140K per year
Klisyri (tirbanibulin)	Microtubule inhibitor	fluorouracil, imiquimod	Treatment of actinic keratosis of the face or scalp	Apply topically to face or scalp once daily for 5 consecutive days	Almirall	$990 per treatment course

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New Molecular Entities, continued

Brand (Generic)	Therapeutic Class	Competitors	Indication(s)	Dosage	Manufacturer	Estimated WAC*
Margenza (margetuximab-cmkb)	HER2/neu receptor antagonist	Herceptin	In combination with chemotherapy, for treatment of adults with metastatic human epidermal growth factor receptor 2 (HER2)-positive breast cancer who have received two or more prior anti-HER2 regimens, at least one of which was for metastatic disease	Recommended dose is 15 mg/kg, administered as an intravenous infusion every 3 weeks (21-day cycle) until disease progression or unacceptable toxicity	MacroGenics	Not available
Orgovyx (relugolix)	Gonadotropin-releasing hormone (GnRH) receptor antagonist	Eligard, Lupron	Treatment of adults with advanced prostate cancer	360 mg orally on day one, followed by 120 mg once daily	Myovant Sciences	$2,313 per 30 tablets
Orladeyo (berotralstat)	Plasma kallikrein inhibitor	Cinryze, Haegarda, Takhzyro	Prophylaxis to prevent attacks of hereditary angioedema (HAE) in patients 12 years and older	150 mg orally once daily	BioCryst	$485K per year

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New Molecular Entities, continued

Brand (Generic)	Therapeutic Class	Competitors	Indication(s)	Dosage	Manufacturer	Estimated WAC*
Tepmetko (tepotinib)	Kinase inhibitor targeting mesenchymal-epithelial transition (MET)	Tabrecta	Treatment of adults with metastatic non-small cell lung cancer with MET exon 14 skipping alterations	450 mg orally once daily until disease progression or unacceptable toxicity	EMD Serono	Not available
Ukoniq (umbralisib)	Kinase inhibitor, dual inhibitor of PI3K-delta and CK1-epsilon	Imbruvica	Treatment of adults with relapsed or refractory marginal zone lymphoma who received at least one anti-CD20-based regimen or relapsed or refractory follicular lymphoma who received at least three prior lines of therapy	800 mg orally once daily	TG Therapeutics	Not available
Verquvo (vericiguat)	Soluble guanylate cyclase (sGC) stimulator	Entresto, Farxiga	Reduces risk of cardiovascular death and heart failure (HF) hospitalization following a hospitalization for HF or outpatient IV diuretics, in adults with symptomatic chronic HF and ejection fraction less than 45%	Starting dose is 2.5 mg orally once daily. Target maintenance dose is 10 mg once daily.	Merck	$550 per month

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New Molecular Entities, continued

Brand (Generic)	Therapeutic Class	Competitors	Indication(s)	Dosage	Manufacturer	Estimated WAC*
Vocabria (cabotegravir)	Integrase strand transfer inhibitor (INSTI),	Isentress, Tivicay	In combination with rilpivirine for short-term treatment of HIV-1 infection in adults who are virologically suppressed on a stable antiretroviral regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine, for use as: oral lead-in to assess the tolerability of cabotegravir prior to administration of Cabenuva or oral therapy for individuals who will miss planned injection dosing with Cabenuva	30 mg orally once daily for approximately 1 month in combination with one tablet of Edurant (rilpivirine) 25 mg orally once daily	ViiV Healthcare	Not available

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New Formulations

Brand (Generic)	Description
Plegridy (peginterferon beta-1a)[I]	Peginterferon beta-1a intramuscular formulation approved for the treatment of relapsing forms of multiple sclerosis.
Posimir (bupivacaine)[I]	Bupivacaine solution approved for infiltration use in adults for administration into the subacromial space under direct arthroscopic visualization to produce post-surgical analgesia for up to 72 hours following arthroscopic subacromial decompression.
Thyquidity (levothyroxine sodium)	Levothyroxine sodium oral solution approved for replacement therapy in hypothyroidism and as an adjunct to surgery and radioiodine therapy in the management of thyrotropin-dependent well-differentiated thyroid cancer.

[I] Injectable

New Indications

Brand (Generic)	Description
Arcalyst (rilonacept)[I]	Arcalyst approved for maintenance of remission of deficiency of interleukin-1 receptor antagonist (DIRA) in adults and pediatric individuals weighing at least 10 kg.
Botox (onabotulinumtoxinA)[I]	Botox approved for the treatment of detrusor (bladder muscle) overactivity associated with a neurologic condition in pediatric individuals 5 years of age and older who have an inadequate response to or are intolerant of anticholinergic medication.
Carbaglu (carglumic acid)	Carbaglu approved for adjunctive treatment of acute hyperammonemia due to propionic acidemia or methylmalonic acidemia.
Benlysta (belimumab)[I]	Benlysta approved for the treatment of active lupus nephritis in adults who are receiving standard therapy.
Darzalex Faspro (daratumumab/hyaluronidase-fihj)[I]	Darzalex Faspro approved for use in combination with bortezomib, cyclophosphamide and dexamethasone (VCd), to treat adults with newly diagnosed light-chain (AL) amyloidosis.
Darzalex Faspro (daratumumab/hyaluronidase-fihj)[I]	Darzalex Faspro approved for the treatment of multiple myeloma in combination with bortezomib, thalidomide, and dexamethasone in newly diagnosed individuals who are eligible for autologous stem cell transplant.

[I] Injectable

New Indications, continued

Brand (Generic)	Description
Edurant (rilpivirine)	Edurant approved in combination with cabotegravir for short-term treatment of human immunodeficiency virus (HIV)-1 infection in adults who are virologically suppressed (HIV-1 RNA less than 50 copies/mL) on a stable antiretroviral regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine, for use as: oral lead-in to assess the tolerability of rilpivirine prior to administration of Cabenuva (cabotegravir/rilpivirine extended-release injection) or oral therapy for individuals who will miss planned injection dosing with Cabenuva.
Enhertu (fam-trastuzumab deruxtecan-nxki)[I]	Enhertu approved for adults with locally advanced or metastatic human epidermal growth factor receptor 2 (HER2)-positive gastric or gastroesophageal (GEJ) adenocarcinoma who have received a prior trastuzumab-based regimen.
Entresto (sacubitril/valsartan)	Entresto approved in chronic heart failure to include individuals with heart failure with reduced ejection fraction (HFrEF), as well as many with heart failure with preserved ejection fraction (HFpEF).
Gavreto (pralsetinib)	Gavreto approved for adult and pediatric individuals 12 years of age and older with advanced or metastatic RET-mutant medullary thyroid cancer (MTC) who require systemic therapy or RET fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate).
Gocovri (amantadine extended-release)	Gocovri approved as an adjunctive treatment to levodopa/carbidopa in individuals with Parkinson's disease experiencing OFF episodes.
Hetlioz (tasimelteon)	Hetlioz capsules approved for the treatment of nighttime sleep disturbances in Smith-Magenis Syndrome (SMS) in adults. An oral suspension formulation was approved for treatment of children with SMS.
Iclusig (ponatinib)	Iclusig approved for adults with chronic-phase (CP) chronic myeloid leukemia (CML) with resistance or intolerance to at least two prior kinase inhibitors.
Kalydeco (ivacaftor)	Kalydeco approved to include additional responsive mutations in people with cystic fibrosis ages 4 months and older.
Kineret (anakinra)[I]	Kineret approved for treatment of deficiency of interleukin-1 receptor antagonist.
Libtayo (cemiplimab-rwlc)[I]	Libtayo approved for individuals with advanced basal cell carcinoma (BCC) previously treated with a hedgehog pathway inhibitor (HHI) or for whom an HHI is not appropriate.

[I] Injectable

New Indications, continued

Brand (Generic)	Description
Nplate (romiplostim)[I]	Nplate approved to increase survival in adults and in pediatric individuals (including term neonates) acutely exposed to myelosuppressive doses of radiation.
Ocrevus (ocrelizumab)[I]	Ocrevus approved for a shorter 2-hour infusion time for individuals for relapsing or primary progressive multiple sclerosis.
Opdivo (nivolumab)[I]	Opdivo approved in combination with cabozantinib as first-line treatment for individuals with advanced renal cell carcinoma.
Panzyga (immune globulin)[I]	Panzyga approved for the treatment of adults with chronic inflammatory demyelinating polyneuropathy (CIDP).
Rapivab (peramivir)[I]	Rapivab approved for the treatment of acute uncomplicated influenza in individuals 6 months and older who have been symptomatic for no more than two days.
Saxenda (liraglutide)[I]	Saxenda approved for chronic weight management among individuals aged 12 years and older who are obese, as defined by specific body mass index (BMI) cut-offs for age and sex that correspond to a BMI 30 kg/m^2 or higher for adults, and who weigh more than 60 kg (132 pounds). Saxenda is an adjunct to a reduced-calorie diet and greater physical activity.
Spritam (levetiracetam)	Spritam approved for the treatment of partial-onset seizures in individuals 4 years of age and older weighing more than 20 kg.
Symdeko (tezacaftor/ivacaftor and ivacaftor)	Symdeko approved to include additional responsive mutations in people with cystic fibrosis ages 6 years and older.
Tagrisso (osimertinib)	Tagrisso approved in adults with non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by a Food and Drug Administration (FDA)-approved test.
Trikafta (elexacaftor/tezacaftor/ivacaftor and ivacaftor)	Trikafta approved to include additional responsive mutations in people with cystic fibrosis ages 12 years and older.
Xalkori (crizotinib)	Xalkori approved for pediatric individuals 1 year of age and older and young adults with relapsed or refractory, systemic anaplastic large cell lymphoma (ALCL) that is anaplastic lymphoma kinase (ALK)-positive.

[I] Injectable

New Indications, continued

Brand (Generic)	Description
Xeomin (incobotulinumtoxinA)[I]	Xeomin approved for the treatment of individuals aged 2 years and older with chronic sialorrhea or drooling.
Xolair (omalizumab)[I]	Xolair approved as add-on maintenance treatment of nasal polyps in adults with inadequate response to nasal corticosteroids.
Xpovio (selinexor)	Xpovio approved in combination with bortezomib and dexamethasone for the treatment of adults with multiple myeloma who have received at least one prior therapy.

[I] Injectable

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