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PharmNOTES

Summary about new FDA-approved products,
new indications, first-time generics,
and WHAT IS IN THE PIPELINE.
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Table of Contents

NEWS

Drug issue	Date	Details
Emergency use authorization for first COVID-19 vaccine	12/11/2020	On December 11, 2020, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the first vaccine for the prevention of coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older. The EUA allows the Pfizer-BioNTech COVID-19 vaccine to be distributed in the United States. Refer to the following sources for additional important details: 1. "Letter of authorization"– Includes details regarding the scope of authorization, product description, the specific conditions that must be met, among other important information. 2. "Fact Sheet for Healthcare Providers Administering Vaccine" – Contains instructions for healthcare providers, dosage and administration details, contraindications, warnings, reported adverse reactions, information to provide to vaccine recipients/caregiver, mandatory requirements for the vaccine administration under EUA, how to report adverse events, information regarding the authority for issuance of the EUA, and the full EUA prescribing information. 3. "COVID-19 Vaccination Program Operational Guidance" – Serves as an interim playbook for state, territorial, tribal, and local public health programs and their partners on how to plan and operationalize a vaccination response to COVID-19 within their jurisdictions. Additional information can be found at the FDA's COVID-19 Vaccines portal and the Centers for Disease and Control Prevention (CDC) website.
Emergency use authorization for second COVID-19 vaccine	12/18/2020	On December 18, 2020, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the second vaccine for the prevention of coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older. The EUA allows the Moderna COVID-19 vaccine to be distributed in the United States. Refer to the following sources for additional important details: 1. "Letter of authorization" 2. "Fact Sheet for Healthcare Providers Administering Vaccine" 3. "COVID-19 Vaccination Program Operational Guidance" Additional information can be found at the FDA's COVID-19 Vaccines portal and the Centers for Disease and Control Prevention (CDC) website.

New FDA Approved Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
Orladeyo™ (berotralstat) Capsules, for oral use	BioCryst Pharmaceuticals, Inc.	12/03/2020

THERAPEUTIC CLASS
Endocrine and metabolic agents

FDA-APPROVE INDICATION(S)
Orladeyo™ is a plasma kallikrein inhibitor indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE) in adults and pediatric patients 12 years and older.

DOSAGE AND ADMINISTRATION
The recommended dose is one capsule (150 mg) taken orally once daily. Dose adjustments are recommended for patients with hepatic impairment, concomitant use with P-gp or BCRP Inhibitors, and persistent gastrointestinal reactions.

DOSAGE FORMS AND STRENGTHS
Capsules: 150 mg, 110 mg.

Orphan status: Orphan

SAFETY PROFILE

CONTRAINDICATIONS
None.

WARNINGS AND PRECAUTIONS
- Risk of QT prolongation with higher-than-recommended dosages

ADVERSE REACTIONS
Most common adverse reactions: abdominal pain, vomiting, diarrhea, back pain, and gastroesophageal reflux disease.

DRUG INTERACTIONS
- P-gp or BCRP inhibitors: Berotralstat is a P-gp and BCRP substrate. Reduce berotralstat dose when co-administered.
- P-gp inducers: Berotralstat is a substrate of P-gp and BCRP. P-gp inducers (e.g., rifampin, St. John's wort) may decrease berotralstat plasma concentration, leading to reduced efficacy of berotralstat. Avoid use with co-administration.

DRUG INTERACTIONS (continuation)
- CYP2D6, CYP3A4 or P-gp Substrates: Berotralstat at a dose of 150 mg is a moderate inhibitor of CYP2D6 and CYP3A4. Berotralstat at a dose of 300 mg is a P-gp inhibitor. Appropriately monitor or dose titrate narrow therapeutic index drugs that are predominantly metabolized by CYP2D6, CYP3A4 or are P-gp substrates when co-administered.

USE IN SPECIFIC POPULATIONS
- Pediatric use: Safety and effectiveness in pediatric patients < 12 years of age have not been established.
- Renal impairment: No dosage adjustment of recommended for patients with mild, moderate or severe renal impairment. Has not been studied in patients with End-Stage Renal Disease or patients requiring hemodialysis, and, therefore is not recommended for use in these patient populations.
- Hepatic impairment: No dosage adjustment of recommended for patients with mild hepatic impairment. In patients with moderate or severe hepatic impairment, reduce berotralstat dose.

New FDA Approved Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
Klisyri™ (tirbanibulin) Ointment, for topical use	Athenex, Inc.	12/14/2020

THERAPEUTIC CLASS
Dermatological agent

FDA-APPROVE INDICATION(S)
Klisyri™ is a microtubule inhibitor indicated for the topical treatment of actinic keratosis of the face or scalp.

DOSAGE AND ADMINISTRATION
The recommended dose is to apply on the face or scalp once daily for 5 consecutive days using 1 single-dose packet per application.

DOSAGE FORMS AND STRENGTHS
Ointment: 1% tirbanibulin, single-dose packets.

Orphan status: N/A

SAFETY PROFILE

CONTRAINDICATIONS
None.

WARNINGS AND PRECAUTIONS
- Ophthalmic adverse reactions
- Local skin reactions

ADVERSE REACTIONS
Most common adverse reactions: local skin reactions, application site pruritus, and application site pain.

DRUG INTERACTIONS
No clinical studies evaluating the drug interaction potential of have been conducted.

USE IN SPECIFIC POPULATIONS
- Pediatric use: Safety and effectiveness for actinic keratosis in subjects less than 18 years of age have not been established. Actinic keratosis is not a condition generally seen within the pediatric population.
- Geriatric use: No overall differences in safety or effectiveness were observed between subjects 65 years of age or older and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

New FDA Approved Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
Margenza™ (margetuximab-cmkb) Injection, for intravenous use	MacroGenics, Inc.	12/16/2020

THERAPEUTIC CLASS
Antineoplastic agent

FDA-APPROVE INDICATION(S)
Margenza™ is a HER2/neu receptor antagonist indicated, in combination with chemotherapy, for the treatment of adult patients with metastatic HER2- positive breast cancer who have received two or more prior anti-HER2 regimens, at least one of which was for metastatic disease.

DOSAGE AND ADMINISTRATION
The recommended dose is 15 mg/kg as an intravenous infusion 120 minutes for the initial dose, then over a minimum of 30 minutes every 3 weeks for all subsequent doses.

DOSAGE FORMS AND STRENGTHS
Injection: 250 mg/10 mL (25 mg/mL) in a single-dose vial.

Orphan status: N/A

SAFETY PROFILE

CONTRAINDICATIONS
None.

WARNINGS AND PRECAUTIONS
- Boxed warning: Left ventricular dysfunction and embryo-fetal toxicity
- Infusion-related reactions

ADVERSE REACTIONS
Most common adverse reactions: fatigue/asthenia, nausea, diarrhea, vomiting, constipation, headache, pyrexia, alopecia, abdominal pain, peripheral neuropathy, arthralgia/myalgia, cough, decreased appetite, dyspnea, infusion-related reactions, palmar-plantar erythrodysesthesia, and extremity pain.

DRUG INTERACTIONS
- Anthracyclines: Patients who receive anthracyclines less than 4 months after stopping treatment may be at increased risk of cardiac dysfunction. While this interaction has not been studied with margetuximab-cmkb, clinical data from other HER2-directed antibodies warrants consideration. Avoid anthracycline-based therapy for up to 4 months after stopping. If concomitant use is unavoidable, closely monitor patient's cardiac function.

USE IN SPECIFIC POPULATIONS
- Pregnancy: Can cause fetal harm. Verify the pregnancy status of females prior to initiation.
- Females of reproductive potential: Pediatric use: Advise females of reproductive potential to use effective contraception during treatment and for 4 months following the last dose.
- Pediatric use: Safety and effectiveness have not been established in pediatric patients.
- Geriatric use: No overall differences in efficacy were observed between patients ≥65 years of age compared to younger patients. There was a higher incidence of Grade ≥ 3 adverse reactions observed in patients age 65 years or older compared to younger patients, as well as adverse reactions associated with potential cardiotoxicity.

New FDA Approved Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
Riabni™ (rituximab-arrx) Injection, for intravenous use	Amgen Inc.	12/17/2020

THERAPEUTIC CLASS
Antineoplastic agent

FDA-APPROVE INDICATION(S)
Riabni™ is a CD20-directed cytolytic antibody indicated for the treatment of non-Hodgkin's Lymphoma (NHL), Chronic Lymphocytic Leukemia (CLL), and Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA).

Refer to full prescribing information for additional details.

DOSAGE AND ADMINISTRATION
The recommended dose varies per patient's diagnosis and BSA. It is to be administered only by a healthcare professional. Refer to full prescribing information for additional details.

DOSAGE FORMS AND STRENGTHS
Injection: 100 mg/10 mL (10 mg/mL) and 500 mg/50 mL (10 mg/mL) solution in single-dose vials.

Orphan status: N/A
Biosimilar to Rituxan™ (rituximab)

SAFETY PROFILE

CONTRAINDICATIONS
None.

WARNINGS AND PRECAUTIONS
- Boxed warning: Fatal infusion-related reactions, severe mucocutaneous reactions, hepatitis B virus reactivation and progressive multifocal leukoencephalopathy
- Tumor lysis syndrome
- Infections
- Cardiovascular adverse reactions
- Renal toxicity
- Bowel obstruction and perforation
- Immunization
- Embryo-fetal toxicity
- Concomitant use with other biologic agents and DMARDS in GPA and MPA

ADVERSE REACTIONS
Most common adverse reactions:
- NHL: infusion-related reactions, fever, lymphopenia, chills, infection and asthenia.
- CLL: infusion-related reactions and neutropenia.
- GPA and MPA: infections, nausea, diarrhea, headache, muscle spasms, anemia, peripheral edema, infusion-related reactions

DRUG INTERACTIONS
Formal drug interaction studies have not been performed with rituximab products.

USE IN SPECIFIC POPULATIONS
- Pregnancy: Can cause fetal harm.
- Females of reproductive potential: Pediatric use: Advise females of reproductive potential to use effective contraception during treatment and for at least 12 months after the last dose.
- Lactation: Advise not to breastfeed.

New FDA Approved Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
Orgovyx™ (relugolix) Tablets, for oral use	Myovant Sciences	12/18/2020

THERAPEUTIC CLASS
Antineoplastic agent

FDA-APPROVE INDICATION(S)
Orgovyx™ is a gonadotropin-releasing hormone (GnRH) receptor antagonist indicated for the treatment of adult patients with advanced prostate cancer.

DOSAGE AND ADMINISTRATION
The recommended dose is a loading dose of 360 mg on the first day of treatment followed by 120 mg taken orally once daily, at approximately the same time each day. Dose adjustments are recommended for drug-drug interactions

DOSAGE FORMS AND STRENGTHS
Tablets: 120 mg.

Orphan status: N/A

SAFETY PROFILE

CONTRAINDICATIONS
None.

WARNINGS AND PRECAUTIONS
- QT/QTc interval prolongation
- Embryo-fetal toxicity
- Laboratory testing

ADVERSE REACTIONS
Most common adverse reactions: hot flush, glucose increased, triglycerides increased, musculoskeletal pain, hemoglobin decreased, alanine aminotransferase (ALT) increased, fatigue, aspartate aminotransferase (AST) increased, constipation, and diarrhea.

DRUG INTERACTIONS
- P-gp Inhibitors: Co-administration increases the AUC and the maximum concentration (Cmax) of relugolix, which may increase the risk of adverse reactions associated with relugolix. Avoid co-administration. If co-administration is unavoidable, take relugolix first, separate dosing by at least 6 hours, and monitor patients more frequently for adverse reactions.

DRUG INTERACTIONS (continuation)
- Combined p-gp and strong CYP3A inducers: Co-administration decreases the AUC and Cmax of relugolix, which may reduce the effects of relugolix. Avoid co-administration. If co-administration is unavoidable, increase the dose of relugolix.

USE IN SPECIFIC POPULATIONS
- Pregnancy: Can cause fetal harm.
- Males of reproductive potential: Pediatric use: Advise male patients with female partners of reproductive potential to use effective contraception during treatment and for 2 weeks after the last dose.
- Pediatric use: Safety and efficacy in pediatric patients have not been established.
- Geriatric use: No overall differences in safety or effectiveness were observed between patients ≥65 years of age compared to younger patients.

New FDA Approved Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
Gemtesa™ (vibegron) Tablets, for oral use	Urovant Sciences	12/23/2020

THERAPEUTIC CLASS
Genitourinary agent

FDA-APPROVE INDICATION(S)
Brand name™ is a _ indicated for the treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency in adults.

DOSAGE AND ADMINISTRATION
The recommended dose is one 75 mg tablet once daily.

DOSAGE FORMS AND STRENGTHS
Tablets: 75 mg.

Orphan status: N/A

SAFETY PROFILE

CONTRAINDICATIONS
- Prior hypersensitivity reaction to vibegron or any components of the product.

WARNINGS AND PRECAUTIONS
- Urinary retention

ADVERSE REACTIONS
Most common adverse reactions: headache, urinary tract infection, nasopharyngitis, diarrhea, nausea, and upper respiratory tract infection.

DRUG INTERACTIONS
- Digoxin: Concomitant use increases digoxin maximal concentrations (Cmax) and systemic exposure as assessed by AUC. Serum digoxin concentrations should be monitored before initiating and during therapy. Titrate the digoxin dose to obtain the desired clinical effect. Continue monitoring digoxin concentrations upon discontinuation and adjust digoxin dose as needed.

USE IN SPECIFIC POPULATIONS
- Pediatric use: Safety and effectiveness in pediatric patients have not been established.
- Geriatric use: No overall differences in safety or effectiveness were observed between patients ≥65 years of age compared to younger patients.
- Renal impairment: No adjustment recommended for patients with mild, moderate, or severe renal impairment. Has not been studied in patients with eGFR <15mL/min/1.73 m2 (with or without hemodialysis) and is not recommended in these patients.
- Hepatic impairment: No adjustment recommended for patients with mild to moderate hepatic impairment. Has not be studied in patients with severe hepatic impairment and is not recommended in this patient population.

New FDA Approved Formulations, Dosage Forms, Combination Products and Other Differences

Drug name / Manufacturer	Therapeutic class	Indication(s)	Date	Comments
Hetlioz LQ™ (tasimelteon) Oral Suspension / Vanda Pharmaceuticals Inc.	Central nervous system agent	Treatment of nighttime sleep disturbances in Smith-Magenis Syndrome (SMS) in pediatric patients 3 years to 15 years of age	12/01/2020	Hetlioz LQ™ is a new oral suspension of the melatonin receptor agonist tasimelteon. Tasimelteon was already available as an oral capsule, branded Hetlioz™. The oral capsule was initially approved for the treatment of non-24-Hour sleep-wake disorder (non-24) in adults and now has been granted approval for the treatment of nighttime sleep disturbances in SMS patients 16 years of age and older. Orphan status: Orphan

New FDA Approved Indications

Drug name / Manufacturer	Therapeutic class	Previous indication(s)	New indication(s)	Date
Hetlioz™ (tasimelteon) Capsules / Vanda Pharmaceuticals Inc.	Central nervous system agent	Treatment of Non-24-Hour Disorder in adults	Treatment of nighttime sleep disturbances associated with Smith-Magenis Syndrome (SMS) in patients 16 years of age and older	12/01/2020
Xolair™ (omalizumab) Subcutaneous Injection / Genentech, Inc.	Respiratory agent; Immunological agent	• Moderate to severe persistent asthma in patients 6 years of age and older • Chronic idiopathic urticaria in adults and adolescents 12 years of age and older	Nasal polyps in adult patients 18 years of age and older	12/01/2020
Gavreto™ (pralsetinib) Capsules / Genentech, Inc.	Antineoplastic agent	Treatment of adult patients with metastatic rearranged during transfection (RET) fusion- positive non-small cell lung cancer (NSCLC) as detected by an FDA approved test	Treatment of adult and pediatric patients 12 years of age and older with advanced or metastatic rearranged during transfection (RET)-mutant medullary thyroid cancer (MTC) who require systemic therapy, or with advanced or metastatic RET fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate)	12/01/2020
Saxenda™ (liraglutide) Injection / Novo Nordisk	Endocrine and metabolic agent	Treatment of obesity	Patient population altered: To include treatment of obesity in adolescents (12–17 years) with a body weight above 60 kg and an initial body mass index (BMI) corresponding to 30 kg/m2 or greater for adults, as an adjunct to reduced-calorie meals and increased physical activity	12/04/2020
Benlysta™ (belimumab) Injection / Human Genome Sciences, Inc. and GlaxoSmithKline	Immunological agent	Treatment of patients with systemic lupus erythematosus	Treatment of adult patients with active lupus nephritis (LN) who are receiving standard therapy	12/16/2020

New FDA Approved Indications

Drug name / Manufacturer	Therapeutic class	Previous indication(s)	New indication(s)	Date
Kineret™ (anakinra) Injection / Sobi	Immunological agent	Treatment of rheumatoid arthritis and neonatal-onset multisystem inflammatory disease (NOMID)	Treatment of deficiency of IL-1 receptor antagonist (DIRA)	12/18/2020
Iclusig™ (ponatinib) Tablets / Ariad Pharmaceuticals, Inc.	Antineoplastic agent	Treatment of chronic myeloid leukemia (CML) and Philadelphia-chromosome positive acute lymphoblastic leukemia (Ph+ ALL)	For adult patients with chronic-phase (CP) CML with resistance or intolerance to at least two prior kinase inhibitors	12/18/2021
Xeomin™ (incobotulinumtoxinA) Injection / Merz Pharmaceuticals	Musculoskeletal agent	Treatment of cervical dystonia, blepharospasm, glabellar lines, upper limb spasticity, and excessive drooling	Patient population altered: Treatment of patients aged 2 years and older with chronic sialorrhea, or drooling	12/18/2021
Xpovio™ (selinexor) Tablets / Karyopharm Therapeutics Inc.	Antineoplastic agent	Treatment of patients adult patients with multiple myeloma (RRMM) and relapsed or refractory diffuse large B-cell lymphoma (DLBCL)	Treatment of adult patients with multiple myeloma who have received at least one prior therapy	12/18/2020
Tagrisso™ (osimertinib) Tablets / AstraZeneca	Antineoplastic agent	• Treatment of adult patients with metastatic EGFR T790M mutationpositive non-small cell lung cancer (NSCLC) , as detected by an FDA-approved test, whose disease has progressed on or after EGFR TKI therapy • First-line treatment of adult patients with metastatic NSCLC whose tumors have EGFR exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test.	As adjuvant therapy after tumor resection in adult patients 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 an FDA-approved test	12/20/2020

New First Time Generic Drug Approval

Drug name / Manufacturer	Therapeutic Class	Indication(s)	Generic for:	Date
Efinaconazole Topical Solution 10% / Perrigo Pharma International DAC; Teva Pharmaceuticals USA, Inc.	Anti-infective agent; Antifungal	Onychomycosis due to dermatophyte, Toenails	Jublia	12/16/2020

PIPELINE

Drug name / Manufacturer	Date	Indication(s)	Comments	Impact
Infigratinib / BridgeBio Pharma, Inc.	12/01/2020	Treatment for: Cholangiocarcinoma of biliary tract	Infigratinib is an orally administered, ATP-competitive, FGFR1-3 tyrosine kinase inhibitor in development for the treatment of individuals with FGFR-driven conditions, including cholangiocarcinoma (bile duct cancer), urothelial carcinoma (bladder cancer) and achondroplasia. The FDA accepted the NDA for infigratinib.	High
Ublituximab / TG Therapeutics, Inc.	12/01/2020	Treatment for: Chronic Lymphocytic Leukemia	Ublituximab (TG-1101) is an investigational glycoengineered anti-CD20 monoclonal antibody in development for the treatment of non-Hodgkin lymphoma (NHL), chronic lymphocytic leukemia (CLL), and relapsing forms of multiple sclerosis (RMS). TG Therapeutics, Inc. has initiated the rolling submission of a BLA for ublituximab.	High
Amivantamab / Janssen	12/03/2020	Treatment for: Non-Small Cell Lung Cancer	Amivantamab is an investigational, fully-human EGFR-MET bispecific antibody in development for the treatment of metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations. Janssen submitted a BLA for amivantamab.	High
Ibrexafungerp / Scynexis, Inc.	12/07/2020	Treatment for: Vaginal Candidiasis	Ibrexafungerp is a first-in-class triterpenoid antifungal agent in development for the treatment of vulvovaginal candidiasis. FDA accepted NDA for ibrexafungerp.	Moderate
Brincidofovir / Chimerix, Inc.	12/07/2020	Treatment for: Smallpox	Brincidofovir is a nucleotide analog broad-spectrum antiviral in development as a medical countermeasure for smallpox. FDA accepted NDA for brincidofovir.	Moderate
Twyneo (benzoyl peroxide and tretinoin) Cream / Sol-Gel Technologies, Ltd.	12/07/2020	Treatment for: Acne	Twyneo (benzoyl peroxide and tretinoin) is a fixed-dose combination of encapsulated benzoyl peroxide, 3%, and encapsulated tretinoin, 0.1%, cream for the treatment of acne vulgaris. FDA accepted NDA for Twyneo.	Moderate

PIPELINE

Drug name / Manufacturer	Date	Indication(s)	Comments	Impact
Odevixibat / Albireo Pharma, Inc.	12/08/2020	Treatment for: Progressive Familial Intrahepatic Cholestasis (PFIC)	Odevixibat is a once-daily, non-systemic ileal bile acid transport inhibitor (IBATi) in development for the treatment of rare pediatric cholestatic liver diseases, including progressive familial intrahepatic cholestasis (PFIC), biliary atresia and Alagille syndrome. Albireo Pharma, Inc. submits a NDA and FDA granted orphan drug designation for odevixibat.	High
TAK-721 (budesonide) Oral Suspension / Takeda Pharmaceutical Company Limited	12/15/2020	Treatment for: Eosinophilic Esophagitis	TAK-721 (budesonide oral suspension) is a novel mucoadherent topically active oral viscous formulation of budesonide in development as a treatment for eosinophilic esophagitis (EoE). FDA accepted NDA and granted orphan drug designation for TAK-721.	High
VP-102 (cantharidin) Topical Solution / Verrica Pharmaceuticals Inc.	12/23/2020	Treatment for: Molluscum Contagiosum	VP-102 (cantharidin) is a topical terpenoid in development for the treatment of molluscum contagiosum. NDA resubmitted.	Moderate
Korsuva (difelikefalin) / Cara Therapeutics, Inc.	12/28/2020	Treatment for: Chronic Kidney Disease-Associated Pruritus	Korsuva (difelikefalin) is a selective peripheral kappa opioid receptor agonist in development for the treatment of moderate-to-severe pruritus in hemodialysis patients. Cara Therapeutics submits a NDA for Korsuva.	Moderate
MydCombi (phenylephrine and tropicamide) Ophthalmic Solution / Eyenovia, Inc.	12/29/2020	Treatment for: Pharmacologic Mydriasis	MydCombi (phenylephrine and tropicamide) is a fixed-combination microdose formulation of the approved mydriatics phenylephrine and tropicamide in development for pharmacologic mydriasis in the eye care practitioner's office. Eyenovia submits a NDA for MydCombi.	Low

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Drug name / Manufacturer	Date	Indication(s)	Comments	Impact
ALKS 3831 (olanzapine and samidorphan) / Alkermes plc	12/28/2020	Treatment for: Schizophrenia, Bipolar Disorder	ALKS 3831 (olanzapine and samidorphan) is an investigational, once-daily, oral atypical antipsychotic combination of an established antipsychotic agent (olanzapine) and a novel μ-opioid receptor antagonist (samidorphan) in development for the treatment of schizophrenia and bipolar I disorder. NDA resubmitted.	Moderate

References

- Food and Drug Administration (www.fda.gov)
- Drugs.com (www.drugs.com)
- IBM Micromedex® (www.micromedexsolutions.com)
- Pharmacist Letter (www.pharmacistletter.com)
- P&T Community (www.ptcommunity.com)