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January 2020

NEW DRUG ENTITY	DRUG NAME	MANUFACTURER	PROPOSED INDICATION	PHARMACOLOGIC CATEGORY	ROUTE OF ADMINISTRATION	ANTICIPATED APPROVAL DATE	CLINICAL PEARLS
No	Rybelsus (semaglutide)	Novo Nordisk; Emisphere	Reduction of Cardiovascular Mortality in patients with Type 2 Diabetes	Antidiabetic: GLP-1 Agonist	Oral	January 2020	Rybelsus gained approval in September 2019 as the first oral glucagon-like peptide. The FDA is currently reviewing results from the PIONEER 6 trial, the cardiovascular outcomes trial with Rybelsus. Results from this trial showed that patients on Rybelsus were not an increased risk for major adverse cardiovascular events (MACE).
No	Dificid (fidaxomicin)	Merck & Co	Treatment of Clostridium Difficile Associated Diarrhea in patients aged 6 months or older	Antibiotic: Macrocyclic	Oral	January 2020	Dificid is already approved as a tablet formulation for the treatment of C. Difficile associated diarrhea in patients over 18 years old. It is now seeking to expand this indication to include patients 6 months to 18 years old. This expanded indication will evaluate both Dificid tables and an oral suspension for use in this younger population.
No	Fiasp (insulin aspart)	Novo Nordisk	Improve glycemic control in Type 1 diabetes in children and adolescents	Insulin	Subcutaneous	January 2020	Fiasp is seeking to expand its already approved indication for use as mealtime insulin for Type 1 Diabetes to include children and adolescents.
Yes	ETC-1002 (bempedoic acid)	Esperion Therapeutics	Hyper-Cholesterolemia	ATP Citrate Lyase Inhibitor	Oral	February 2020	Bempedoic acid is activated in the liver to inhibit ATP-Citrate Lyase (ACL), which acts upstream of HMG-CoA reductase. This causes an upregulation of LDL-receptors, increasing LDL-cholesterol clearance.
Yes	Ezetimibe (bempedoic acid)	Esperion Therapeutics	Hyper-Cholesterolemia	ATP Citrate Lyase Inhibitor/Intestinal Cholesterol Absorption Inhibitor	Oral	February 2020	Bempedoic acid is also being evaluated for use with Ezetimibe in a fixed-dose combination for patients with Atherosclerotic Cardiovascular Disease (ASCVD) or those at high risk for ASCVD.
Yes	Barhemsys (amisulpride)	Acacia Pharma	Post-Operative Nausea & Vomiting	Antiemetic	Intravenous	February 2020	Acacia has resubmitted the NDA for Barhemsys (amisulpride) designating a new supplier of amisulpride. The previous two submissions were denied due to not meeting the FDA standards for the manufacturing and production process.

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No	Empagliflozin/ Linagliptin/ Metformin Extended-Release	Eli Lilly; Boehringer Ingelheim	Improve Glycemic Control in Type 2 Diabetes	Antidiabetic: SGLT2 Inhibitor; DPP-4 Inhibitor; Biguanide	Oral	February 2020	Empagliflozin/Linagliptin/Metformin extended-release is an investigational fixed dose combination tablet seeking approval for the treatment of adults with Type 2 Diabetes (T2DM). If approved, it would be one of the first single-pill options with three mechanisms of action for blood glucose management in T2DM.
Yes	ITCA 650 (exenatide)	Intarcia Therapeutics	Improve Glycemic Control in patients with Type 2 Diabetes	Antidiabetic: GLP-1 Agonist	Implant	March 2020	If approved, ITCA 650 would be a new twice-yearly glucagon-like peptide-1 (GLP-1) agonist delivery system for maintenance therapy of patients with Type 2 Diabetes. The implant is a small match stick-sized osmotic mini pump delivery system that is placed beneath the patient's skin in the abdominal area.
Yes	Fintepla (fenfluramine)	Zogenix	Dravet Syndrome	Serotonin Reuptake Inhibitor	Oral	March 2020	Fintepla (fenfluramine) is being reviewed as a low-dose oral solution for the treatment of seizures associated with Dravet Syndrome. Fenfluramine was originally used as an appetite suppressant but was withdrawn in the 1990s due to cardiovascular safety concerns. In more recent trial data, Fintepla shows to reduce monthly seizure frequency without cardiovascular toxicity.
Yes	HTX-011 (bupivacaine/ meloxicam)	Heron Therapeutics	Post-Operative Pain	Anesthetic/NSAID	Injectable	March 2020	HTX-011 is a long-acting fixed dose combination of a local anesthetic (bupivacaine) and a non-steroid anti-inflammatory (meloxicam) that has been resubmitted to the FDA approval for post-operative pain management. This drug was originally submitted in 2018, but the FDA requested additional information regarding chemistry, manufacturing, and controls.

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No	Triferic (ferric pyrophosphate citrate)	Rockwell Medical	Anemia in End Stage Renal Disease (ESRD)	Supplement: Iron	Intravenous	March 2020	Triferic is the only therapy approved by the FDA to replace iron and maintain hemoglobin in adult hemodialysis patients with Chronic Kidney Disease. The approved formulation is available as a hemodialysate. The intravenous (IV) and peritoneal dialysate formulations are now under review.
Yes	Bronchitol (mannitol)	Pharmaxis; Chiesi	Cystic Fibrosis	Mucolytic	Inhaled	1Q20	Bronchitol is a dry powder for inhalation that works by drawing water into airways in patients with Cystic Fibrosis (CF), thus moistening and thinning the sticky mucus found in CF patients and helping them cough easier. The therapy has been approved in CF patients over 6 years old in Australia and over 18 years old throughout the European Union and in Israel.
No	Ozempic (semaglutide)	Novo Nordisk	Reduce Cardiovascular Events in patients with Type 2 Diabetes	Antidiabetic: GLP-1 Agonist	Subcutaneous	1Q20	Ozempic is pursing an indication to reduce the risk of major adverse cardiovascular events (MACE) such as heart attack, stroke, or death in adults with Type 2 Diabetes and established cardiovascular disease.
No	Trulicity (dulaglutide)	Eli Lilly	Reduce Cardiovascular Events in patients with Type 2 Diabetes	Antidiabetic: GLP-1 Agonist	Subcutaneous	1Q20	REWIND is the longest cardiovascular outcome trial in the GLP-1 agonist class with a median of 5.4 years. In the REWIND trial, Trulicity showed a 12% reduction in major CV events, a composite endpoint of non-fatal myocardial infarction, non-fatal stroke or CV death.
Yes	MenQuadfi (meningococcal conjugate vaccine)	Sanofi	Meningococcal Disease	Vaccine	Intramuscular	April 2020	MenQuadfi Meningococcal (Groups A, C, Y, and W) Polysaccharide Tetanus Toxoid Conjugate Vaccine is seeking approval to help prevent Meningococcal Meningitis for ages 2 years and older.

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Yes	Ongentys (opicapone)	Bial; Neurocrine	Motor Deficit associated with Parkinson's Disease	Catechol-O-Methyl-Transferase (COMT) Inhibitor	Oral	April 2020	Ongentys is a once daily add-on therapy to levodopa for adults with Parkinson's Disease or with movement problems. It inhibits an enzyme called catechol-o-methyltransferase (COMT) that breaks down levodopa. Ongentys has been approved for use in Europe since 2016.
Yes	Remimazolam	Ono Pharmaceutical; Cosmo Technologies Ltd; Paion; Aries Pharmaceuticals	Procedural Sedation	Benzodiazepine	Intravenous	April 2020	Remimazolam is an ultra-short-acting intravenous (IV) benzodiazepine sedative. It is currently being studied in colonoscopy, bronchoscopy, and other general anesthesia procedures for its rapid onset and offset action as well as its cardio-respiratory safety profile.
Yes	Dasotraline	Sunovion; Sumitomo Dainippon Pharma	Moderate to Severe Binge Eating Disorder	Serotonin/ Norepinephrine/ Dopamine Reuptake Inhibitor (SNDRI)	Oral	May 2020	Dasotraline is a new chemical entity that inhibits presynaptic reuptake of dopamine and norepinephrine in the central nervous system and is being evaluated for the treatment of adults with moderate to severe Binge Eating Disorder (BED). It is estimated that BED affects 4.1 million people in the U.S.
Yes	Amphora (citric acid/ L-lactic acid/ potassium bitartrate)	Evofem	Pregnancy Prevention	Contraception: pH Buffer	Intravaginal	May 2020	Amphora is a multipurpose vaginal pH regulator (MVP-R) for the prevention of pregnancy. This agent is designed to regulate vaginal pH within the normal range of 3.5 to 4.5, even in the presence of semen, which normally raises the vaginal pH to 7 or 8. If approved, Amphora would provide a new hormone-free, on-demand, prescription contraceptive option for women.
No	Orilissa (elagolix)	AbbVie; Neurocrine	Uterine Fibroids	Hormone: Gonadotropin-Releasing Hormone (GnRH) Antagonist	Oral	2Q20	A second indication for Orilissa has been submitted to the FDA for review. They are seeking approval for the treatment of heavy menstrual bleeding associated with uterine fibroids, which are non-cancerous, hormonally-responsive muscle tissue tumors in the uterus.

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No	Bimatoprost Sustained Release Implant	Allergan	Glaucoma/Ocular Hypertension	Prostaglandin Analog	Ophthalmic Implant	1H20	Bimatoprost sustained release is a potential first-in-class biodegradable implant for the reduction of intraocular pressure (IOP) in patients with primary open-angle glaucoma or ocular hypertension. Bimatoprost SR implant administered on day 1, week 16 and week 32 showed non-inferiority when compared to timolol twice daily for 20 months.
Yes	VP-102 (cantharidin)	Verrica	Molluscum Contagiosum	Blistering Agent	Topical	July 2020	Cantharidin is a blistering agent that has been used since the 1950s to treat Molluscum Contagiosum (viral skin infection) and warts. However, the it was removed it from the market in 1962 after the FDA required manufacturers to submit efficacy data for their products. If approved, Cantharidin would be the first FDA-approved treatment for this viral skin disease.
Yes	RVL-1201 (oxymetazoline hydrochloride)	RevitaLid; Osmotica; Vertical Pharmaceuticals	Blepharoptosis	Anti-Inflammatory Agent	Ophthalmic	July 2020	Oxymetazoline HCl ophthalmic solution is seeking approval for the treatment of Acquired Blepharoptosis, also known as droopy eyelid or ptosis. This is a once-daily formulation, a direct acting adrenergic receptor agonist, which when administered to the eye is believed to selectively target the Müller's muscle and elevate the upper eyelid.
Yes	UX007 (triheptanoin)	Ultragenyx	Long-Chain Fatty Acid Oxidation Disorders (Faod)	Lipid Replacement Therapy	Oral	July 2020	Triheptanoin is a medium-chain triglyceride that bypasses the genetic block in the long-chain fatty acid metabolism. Patients with long-chain fatty acid oxidation disorders are unable to convert long-chain fatty acids into energy, which can lead to severe glucose depletion.

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No	Ocaliva (obeticholic acid)	Intercept Pharma	Treatment of Liver Fibrosis due to Non-Alcoholic Steatohepatitis (NASH)	Farnesoid X Receptor (FXR) Agonist	Oral	July 2020	If approved, Ocaliva would become the first FDA-approved therapy for the treatment of patients with liver fibrosis due to Non-Alcoholic Steatohepatitis (NASH). NASH is a progressive liver disease caused by excessive fat accumulation in the liver that incudes chronic inflammation, resulting in fibrosis that can lead to cirrhosis, eventual liver failure, cancer and death.
Yes	Viaskin Peanut Patch	DBV Technologies	Allergy to Peanuts	Allergen Immunotherapy	Topical	August 2020	Viaskin Peanut has been resubmitted with additional data, per the FDA's 2018 request, regarding manufacturing procedure and quality control data. In the PEPTIDES trial, 238 pediatric patients were given Viaskin 250mcg over 12 months and had a 35% responder rate compared to the 118 patients given placebo with a 13.6% responder rate.
Yes	TRC101 (veverimer)	Tricida	Metabolic Acidosis	Acid Binder	Oral	August 2020	Veverimer is a non-absorbed polymer that treats metabolic acidosis by binding hydrochloric acid in the gastrointestinal tract and removing it from the body through fecal excretion. Veverimer does not deliver sodium which makes it a potential therapy suitable for Chronic Kidney Disease patients.
Yes	Winlevi (clascoterone)	Cassiopea; Cosmo Technologies	Acne Vulgaris	Antiandrogens	Topical	August 2020	Winlevi is an anti-androgen treatment seeking approval for the treatment of acne. It is a topical therapy that penetrates the skin to reach the androgen receptors of the sebaceous gland. The goal of Winlevi is to be an effective and safe anti-androgen for both men and women that does not have systemic effects.

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No	Spravato (esketamine hydrochloride)	Janssen	Adults with Major Depressive Disorder (MDD) who have active suicidal ideation intent	Antidepressant: NMDA Receptor Antagonist	Nasal	August 2020	Spravato is being reviewed for a second indication: rapid reduction of depressive symptoms in adults with Major Depressive Disorder (MDD) who have active suicidal ideation intent. If approved, Spravato would be the first treatment for this severely ill population who historically have been excluded from anti-depressant clinical trials.
No	Trelegy Ellipta (fluticasone furoate/ umeclidinium bromide/ vilanterol trifenatate)	GSK; Theravance; Innoviva	Asthma	Respiratory: Corticosteroid/ LABA/LAMA	Inhaled	August 2020	Trelegy Ellipta was first approved in 2017 for the treatment of Chronic Obstructive Pulmonary Disease. It is now being reviewed for a second indication as a once-daily, single-inhaler triple therapy for the treatment of asthma in adults.
Yes	ALKS 3831 (olanzapine/ samidorphan)	Alkermes	Bipolar Disorder I or II & Schizophrenia	Atypical Antipsychotic/ Opioid Antagonist	Oral	4Q20	ALKS 3831 is an investigational, once-daily, oral atypical antipsychotic drug candidate designed to provide the efficacy of olanzapine while mitigating olanzapine-associated weight gain. ALK 3831's submission includes data to support an indication for the treatment of Schizophrenia, and an indication for the treatment of manic or mixed episodes associated with Bipolar 1 Disorder as monotherapy or adjunct to lithium or valproate and for maintenance treatment of Bipolar 1 Disorder.
Yes	Remune (HIV vaccine)	Immune Response; BioPharma	HIV Infection	Vaccine	Intramuscular	4Q20	Remune is a therapeutic vaccine that is designed to block the immune system's response to HIV antigens in people with the HIV virus.
Yes	SPN-812 (viloxazine hydrochloride)	Supernus Pharmaceuticals	Attention Deficit Hyperactivity Disorder (ADHD)	Norepinephrine Reuptake Inhibitor	Oral	4Q20	Viloxazine has been marketed for years in Europe as an antidepressant and is trying to be approved for use in the treatment of ADHD in the U.S.