

Emerging Therapeutics: DrugWatch

August 2021

Pipeline Drugs: A Closer Look

In each issue of DrugWatch, the Emerging Therapeutics Department highlights one traditional and one specialty pipeline product with near-term approval expected.

Traditional Pipeline	
Drug: Comirnaty (SARS-CoV-2 vaccine)	Action Date: Sep. 6, 2021
Manufacturer: BioNTech/Pfizer	Route: Intramuscular
Indication: Prevention of COVID-19 in individuals aged 16 years and older	
Comments:	
Pfizer and BioNTech are seeking formal FDA approval for Comirnaty, an mRNA based vaccine against coronavirus disease 2019 (COVID-19). The mRNA instructs the cell to produce proteins of the S antigen (a piece of the spike protein unique to SARS-CoV-2) to stimulate an immune response. Although the vaccine is currently available through an Emergency Use Authorization (EUA), this application is to convert the vaccine to full FDA approval. This application was granted a priority review. As a result, the FDA has set a Prescription Drug User Fee Act (PDUFA) target action date of Sep. 6, 2021. FDA is expected to rule on approval on or before this date.	
Specialty Pipeline	
Drug: bimekizumab	Action Date: Oct. 15, 2021
Manufacturer: UCB	Route: Subcutaneous
Indication: Psoriasis	
Comments:	
UCB's bimekizumab is an interleukin (IL)-17A and IL-17F inhibitor in development for the treatment of moderate-to-severe plaque psoriasis. Approximately eight million Americans have plaque psoriasis and 35% of the cases are moderate-to-severe. Bimekizumab is self-administered as a subcutaneous (SC) injection once every four weeks. In four Phase III trials, bimekizumab demonstrated that it is more effective than placebo, Stelara® (ustekinumab – Janssen), Humira® (adalimumab – AbbVie) and Cosentyx® (secukinumab – Novartis). Approval is expected by Oct. 15, 2021.	

FDA Action Dates

Products in the table below are currently under FDA review with near-term FDA action dates.

Drug	Manufacturer	Use	S	Action Date
bupropion/dextromethorphan	Axsome	Depression		Aug-22
Xarelto (rivaroxaban)*	Janssen	Peripheral Arterial Disease		Aug-26
Korsuva (difelikefalin)	Enteris/Cara	Pruritus		Aug-29
treosulfan	Medexus/Medac	Stem Cell Transplantation		Aug. 2021
Lantidra (donislecel)	CellTrans	Diabetes, Type 1		Aug. 2021
Comirnaty (COVID-19 Vaccine)	Pfizer/BioNTech	COVID-19 Vaccine		Sep-06
Trudhesa (dihydroergotamine)	Impel	Migraine		Sep-06
Nefecon (budesonide)	Calliditas	IgA Nephropathy		Sep-15
Lucentis Biosimilar	Biogen/SB	AMD	S	Sep-18
Brukina (zanubrutinib)*	BeiGene	Marginal Zone Lymphoma	S	Sep-19
Jakafi Cream (ruxolitinib cream)	Incyte	Atopic dermatitis		Sep-22
Ycanth (cantharidin Topical)	Verrica	Molluscum Contagiosum		Sep-23
lonapegsomatropin	Ascendis	Growth Hormone	S	Sep-25
maralixibat	Mirum	ALGS-Associated Pruritus	S	Sep-29
atogepant	Allergan	Migraine		3Q 2021
reltecimod	Atox Bio	Necrotizing Infection		Sep-30
Xeljanz/XR (tofacitinib)*	Pfizer	Ankylosing Spondylitis	S	3Q 2021
Tecartus (brexucabtagene autoleucl)*	Kite/Gilead	ALL	S	Oct-01
avacopan	ChemoCentryx	Vasculitis	S	Oct-07
tisotumab vedotin	Genmab/Seagen	Cervical Cancer	S	Oct-10
bimekizumab	UCB	Psoriasis	S	Oct-15
sodium oxybate, C.R.	Avadel	Narcolepsy	S	Oct-15
varenicline	Oyster Point	Dry Eyes	S	Oct-17
narsoplimab	Omeros	Microangiopathy	S	Oct-17
Brukina (zanubrutinib)*	BeiGene	Macroglobulinemia	S	Oct-18
Dextenza (dexamethasone, SR)*	Ocular	Allergic Conjunctivitis		Oct-18
Tyvaso DPI (treprostinil dpi)	United	PAH	S	Oct-19

* = New Indication; "S" = Specialty

SB=Samsung Bioepis; ALL= Acute Lymphoblastic Leukemia; PAH=Pulmonary Arterial Hypertension; AMD= Age-related Macular Degeneration; ALGS = Alagille Syndrome

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FDA Updates

Recent New Drug Approvals

Date	Drug	Manufacturer	Use	S
Jul. 21	fexinidazole	Sanofi	Sleeping Sickness	
Jul. 27	Twynéo (benzoyl peroxide / tretinoin)	Sol-Gel	Acne	
Jul. 30	Saphnelo (anifrolumab-fnia)	AstraZeneca	Systemic Lupus Erythematosus	S
Jul. 30	Uptravi (selexipag) IV	Actelion	Pulmonary Arterial Hypertension	S
Aug. 06	Nexviazyme (avalglucosidase alfa)	Sanofi	Pompe Disease	S
Aug. 13	Welireg (belzutifan)	Merck	Renal Cell Carcinoma	S
Aug. 16	TicoVac (tick-borne encephalitis vaccine)	Pfizer	Tick-Borne Encephalitis	

"S" = Specialty

Recent Generic Launches

Date	Drug	Manufacturer	Use	Annual Sales [^]
Aug. 04	Duexis	Horizon Pharma	Pain/Inflammation	\$857

[^] = Million

Patent Expirations: 2021

In 2021, an estimated \$10 billion in first-time generics could become available. The following table includes products losing patent protection in 2021.

Drug	Manufacturer	Use	Patent Expiration	Annual Sales [^]
Amitiza	Sucampo	GI Disorders	AG Only	\$325
Zyclara 3.75%	Medicis	Skin Conditions	Generic	\$10
Qudexy XR	Upsher-Smith	Seizures	Generic	\$55
Glucagon	Lilly	Hypoglycemia	Generic	\$154
Northera	Lundbeck	Low Blood Pressure	Generic	\$425
Xulane	Mulan	Contraceptive Patch	Generic	\$345
Hysingla ER	Purdue	Pain	Generic	\$84
Azopt	Alcon	Glaucoma	Generic	\$184
Lyrica CR	Pfizer	Pain	Generic	\$3
Absorica	Ranbaxy	Acne	Generic	\$176
Bepreve	ISTA	Ophthalmic Allergies	Generic	\$38
Intelence	Janssen	HIV	Generic	\$134
Perforomist	Dey	COPD	Generic	\$291
Brovana	Sunovion	COPD	Generic	\$552
Chantix	Pfizer	Smoking Cessation	Pending	\$1,222
Durezol	Sirion	Ophthalmic Inflammation	Pending	\$106
Sutent	Pfizer	Cancer	Aug. 16	\$305
Bystolic	Forest	High Blood Pressure	Sep. 17	\$1,076
Jevtana Kit	Sanofi	Cancer	Sep. 27	\$223
Innopran XL	ANI	High Blood Pressure	Oct. 04	\$31
Brovana	Sunovion	Asthma	Nov. 09	\$479
Gilenya 0.25mg [#]	Novartis	Multiple Sclerosis	Nov. 11	\$0
Jublia	Dow Pharma	Nail Fungal infections	Dec. 06	\$222
Cayston	Gilead	Cystic Fibrosis	Dec. 20	\$10
Afinitor 10mg	Novartis	Cancer	4Q 2021	\$416
Byetta	AstraZeneca	Diabetes	2021-2022	\$134
Daliresp	AstraZeneca	COPD	2021	\$231
Forteo	Lilly	Osteoporosis	2021-2022	\$883
Restasis	Allergan	Dry Eye Disease	2021	\$2,244
Toviaz	Pfizer	Overactive Bladder	2021	\$258

[^] Millions (IMS sales [2019]); * = Settlement Agreement; Pending = Generic approved but launch is pending

"Generic" = Generic available; (AG) = Authorized product only

"Expired" = no active patents or exclusivities listed in FDA's Orange Book.

[#] = strength currently not marketed