

DD	Medicijn	Producent	Approval / CRL / Delayed	Source
3/1/2021	Stimufend (MSB11455 (biosimilar pegfilgrastim))	Fresenius Kabi	?	
3/1/2021	ropeginterferon alfa-2b	PharmaEssentia	15 maart 2021 CRL	https://www.targetedonc.com/view/fda-issues-crl-for-ropeginterferon-alfa-2b-njft-bla-in-pv
3/2/2021	KP415 AZSTARYS	KemPharm	2 maart 2021 Approval	https://www.globenewswire.com/news-release/2021/03/03/2185820/0/en/KemPharm-Announces-FDA-Approval-of-AZSTARYS-serdexmethylphenidate-and-dexmethylphenidate-capsules-for-oral-use-CII-A-New-Once-Daily-Treatment-for-ADHD.html
1Q2021	FYB201 (ranibizumab biosimilar)	Coherus Biosciences	?	
3/18/2021	Ponesimod PONVORY	Janssen	19 maart 2021 Approval	https://www.jnj.com/janssen-announces-u-s-fda-approval-of-ponvory-ponesimod-an-oral-treatment-for-adults-with-relapsing-multiple-sclerosis-proven-superior-to-aubagio-teriflunomide-in-reducing-annual-relapses-and-brain-lesions
3/20/2021	Roxadustat	FibroGen Inc. and AstraZeneca	3 maart 2021 delayed	https://www.fiercepharma.com/marketing/capricious-fda-spooks-fibrogen-astrazeneca-last-minute-roxadustat-adcom-cuing-another
3/21/2021	fosdenopterin (BBP-870)	Origin Biosciences	1 maart 2021 approval	https://www.thepharmaletter.com/article/fda-green-lights-first-treatment-for-molybdenum-cofactor-deficiency-type-a
3/27/2021	Zegalogue (dasiglucagon) HypoPal Rescue Pen	Zealand Pharma	22 maart 2021 approval	https://www.globenewswire.com/news-release/2020/05/22/2037818/0/en/Zealand-Pharma-announces-FDA-acceptance-of-New-Drug-Application-for-the-dasiglucagon-HypoPal-rescue-pen-for-treatment-of-severe-hypoglycemia.html
3/27/2021	idecabtagene vicleucel (bb2121, ide-cel)	Bristol-Myers Squibb and Bluebird Bio	27 maart 2021 approval	https://www.cancernetwork.com/view/fda-approves-car-t-cell-therapy-idecabtagene-vicleucel-for-previously-treated-multiple-myeloma

3/31/2021	tivozanib	Aveo Oncology	10 maart 2021 approval	https://www.fda.gov/drugs/drug-approvals-and-databases/fda-approves-tivozanib-relapsed-or-refractory-advanced-renal-cell-carcinoma
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