

BIOSIMILAR PIPELINE

GENERIC NAME	BRAND NAME	MANUFACTURER	INDICATION(S)	ROUTE OF ADMINISTRATION	ANTICIPATED APPROVAL DATE*
Oncology					
MYL-14020	N/A (Avastin® biosimilar)	Mylan NV and Biocon Ltd.	Oncology	IV	Delayed- 2021
SB8	N/A (Avastin® biosimilar)	Samsung Bioepis and Merck	Oncology	IV	1H2021
FKB238	N/A (Avastin® biosimilar)	Centus Biotherapeutics	Oncology	IV	1H2021
BAT-1706	N/A (Avastin® biosimilar)	Bio-thera solutions	Oncology	IV	November 2021
Blood modifiers					
MSB11455	Stimufend® (Neulasta® biosimilar)	Fresenius Kabi	Neutropenia	SC	March 2021
filgrastim kashiv	N/A (Neupogen® biosimilar)	Adello Biologics	Hematology	IV or SC	2021
TPI-120	N/A (Neulasta® biosimilar)	Amneal and Kashiv (Adello)	Neutropenia	SC	2022
Ophthalmology					
FYB201	N/A (Lucentis® biosimilar)	Coheres biosciences/bioeq	Age-related macular degeneration	Injection into the eye	2021
SB11	N/A (Lucentis® biosimilar)	Samsung Bioepis	Age-related macular degeneration	Injection into the eye	September 2021
Autoimmune					
AVT02	N/A (Humira® biosimilar)	Alvotech	Autoimmune	SC	September 2021
CHS-1420	N/A (Humira® biosimilar)	Coherus	Autoimmune	SC	September 2021

FDA APPROVED GENE/CELL THERAPY NEW PRODUCT APPROVALS

GENERIC NAME	BRAND NAME	MANUFACTURER	INDICATION(S)	ROUTE OF ADMINISTRATION	MONTH APPROVED
lisocabtagene maraleucel (liso-cel)	Breyanzi™	Bristol-Myers Squibb	R/R large B cell lymphoma	IV	February 2021
brexucabtagene autoleucel	Tecartus™	Kite	Mantle cell lymphoma	CAR T-cell therapy	July 2020
onasemnogene abeparvovec-xioi	Zolgensma™	AveXis	Spinal muscular atrophy	IV	May 2019
voretigene neparvovec-rzyl	Luxturna®	Spark Therapeutics	Biallelic RPE65 mutation-associated retinal dystrophy	Subretinal injection	December 2017
axicabtagene ciloleucel	Yescarta®	Kite	Large B-cell lymphoma	IV	October 2017
tisagenlecleucel	Kymriah®	Novartis	Acute lymphoblastic leukemia	IV	August 2017

GENE/CELL THERAPY 2021 PIPELINE

GENERIC NAME	BRAND NAME	MANUFACTURER	INDICATION(S)	ROUTE OF ADMINISTRATION	ANTICIPATED APPROVAL DATE
RVT-802	N/A	Enzyvant	Pediatric congenital athymia	IV	2021
idecabtagene vicleucel (bb2121, ide-cel)	N/A	Bristol-Myers Squibb and bluebird bio	Multiple myeloma	CAR-T	2021
loncastuximab tesirine (Lonca)	N/A	ADC Therapeutics	Relapsed or refractory diffuse large B-cell lymphoma (DLBCL)	IV	2021

YELLOW
STICKER

REFERENCES

- <https://www.globenewswire.com/news-release/2021/02/25/2182845/0/en/Sarepta-Therapeutics-Announces-FDA-Approval-of-AMONDYS-45-casimersen-Injection-for-the-Treatment-of-Duchenne-Muscular-Dystrophy-DMD-in-Patients-Amenable-to-Skipping-Exon-45.html>
- https://icer.org/wp-content/uploads/2020/10/ICER_DMD_Evidence-Report_071619.pdf
- <https://www.globenewswire.com/news-release/2021/02/28/2183818/0/en/BridgeBio-Pharma-and-Affiliate-Origin-Biosciences-Announce-FDA-Approval-of-NULIBRY-fosdenopterin-the-First-and-Only-Approved-Therapy-to-Reduce-the-Risk-of-Mortality-in-Patients-wit.html>
- <https://www.prnewswire.com/news-releases/fda-approves-oncopeptides-pepaxto-melphalan-flufenamide-for-patients-with-triple-class-refractory-multiple-myeloma-301237310.html>
- <https://www.fiercepharma.com/pharma/aveo-s-tivozanib-now-approved-as-fotivda-will-hit-market-after-years-setbacks>
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- <https://endpts.com/fibrogen-shares-skid-lower-as-a-surprise-adcomm-raises-risks-on-roxa-ok/>
- <https://www.argenx.com/news/argenx-issues-statement-concerning-efgartigimod>
- <https://www.fiercepharma.com/special-report/top-10-drugs-losing-u-s-exclusivity-2021>