

2020 Biosimilars Blossoms in the US Market

The U.S. biosimilar market is just beginning

Starting with 2015 Zarxio, Sandoz's Neupogen biosimilar, the U.S. FDA has approved 26 biosimilars.

Expectations have been high since more than 50 percent of the shipments are from the US market, yet result so far have been disheartening. The approval rate for a biosimilar, however, is increasing annually.

U.S. biosimilars are also speeding up, starting in 2020. Currently, 26 biosimilars have obtained marketing licenses. And among 26 items, fifteen of them, including Avastin biosimilar Mvasi, Herceptin biosimilar Kanjinti, Rituxan biosimilar Truxima, are already on the U.S. market since 2019. It is worth to note the high market share of these anticancer biosimilars in the short term since their approval.

Anticancer biosimilars gain high market share

In 2019, as Roche's anticancer trios, Rituxan, Herceptin, and Avastin's patents expired one after another, anticancer biosimilars entry to the market followed. In July, Avastin's biosimilar Mvasi and Herceptin biosimilar Kanjinti, and in Nov. Rituxan biosimilars Truxima has begun to go on sale in the U.S. market.

According to Symphony Health's prescription data, approximately \$40 million worth of Mvasi was prescribed within six months of the released date, recording 16% of Avastin's market share.

Herceptin biosimilar Kanjinti also controls 12% of the total market in just six months after its launch.

Considering that Remicade biosimilar Inflectra only had 8% of the U.S. market after its launch in November 2016, recent biosimilars shows the rapid growth within its market.

Performance



Growth



Momentum



Valuation



Stock symbol	Bloomberg target price	CP(02/27)
NYSE: PFE Pfizer Inc.	43.15 USD	33.93

Pfizer Inc. Financial Data

Million USD	2018	2019	2020F	2021F
Sales	53,647	51,750	47,150	48,087
Profit	21,137	22,058	21,607	21,605
Net Profit	17,477	16,733	16,301	17,556
ESP(USD)	2.92	2.95	2.91	3.07
ESP(YOY, %)	10.2	1.0	(1.4)	5.5
ROE (%)	16.5	25.5	24.3	27.3
PER	19.3	17.4	13.1	12.4
PBR	3.9	3.9	3.4	3.2
Dividend Rate	3.2	3.7	3.9	4.1

Non-GAAP, forecast based on market average estimate
Source: Bloomberg



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Summary of FDA approved biosimilars

Approval Date	Biosimilar	Development Company (biosimilar)	Original	Component	Development Company (original)	Patent Expiration Date (Original)	Enter US Market	US Market Status
2015-03-06	Zarxio	Sandoz	Neupogen	Filgrastim	Amgen	2013.12	o	2015 Sept, frist biosimilar to get FDA approval and currently on the US market
2016-04-05	Inflectra	Celltrion	Remicade	Infliximab	J&J	2018.09	o	2016 Nov, frist Remicade biosimilar to enter the US market
2016-08-30	Ereizi	Sandoz	Enbrel	Etanercept	Amgen	2028.11	x	Currently in lawsuit with Amgen regarding about Enbrel's patent
2017-09-14	Mvasi	Amgen, Allergan	Avastin	Bevacizumab	Genetech	2019.07	o	2019 July, first antiviral biosimilar released on the marketed
2017-12-01	Ogivri	Mylan	Herceptin	Trastuzumab	Genetech	2019.02	o	First Herceptin biosimilar to get FDA approval. 2019 Dec, 2nd biosimilar to enter US market, following Kanjinti
2017-12-14	Ixifi	Pfizer	Remicade	Infliximab	J&J	2018.09	x	No intention to enter the US market
2018-05-16	Retacrit	Pfizer	Epogen	Epoetin Alfa	Amgen	2013.11	o	2018 Nov, first Epogen biosimilar to enter the US market
2018-06-05	Fulphila	Mylan	Neulasts	Pegfilgrastim	Amgen	2015.1	o	2018 July, first Neulasts biosimilar released on the market
2018-07-20	Nivestym	Pfizer	Neupogen	Filgrastim	Amgen	2013.12	o	2018 Oct, 2nd Neupogen biosimilar released on the market
2018-10-31	Hyrimoz	Sandoz	Humira	Adalimumab	AbbVie	2016.12	x	2023 Sept, 4th Humira biosimilar to be released (scheduled)
2018-11-02	Udenyca	Coherus	Neulasts	Pegfilgrastim	Amgen	2015.1	o	2019 Jan, 2nd Neulasta biosimilar released on the market
2018-12-15	Herzuma	Celltrion	Herceptin	Trastuzumab	Roche	2019.06	x	N/A

2019-01-19	Ontruzant	Samsung Bioepis	Herceptin	Trastuzumab	Roche	2019.06	x	No intention to enter the US market
2019-03-12	Trazimera	Pfizer	Herceptin	Trastuzumab	Roche	2019.06	o	2020 Feb, 2nd Herceptin biosimilar to enter the US market
2019-04-25	Eticovo	Samsung Bioepis	Enbrel	Etanercept	Amgen	2028.11	x	2nd Enbrel biosimilar to get FDA approval. Currently in lawsuit with Amgen regarding about Enbrel's patent
2019-06-13	Kanjinti	Amgen, Allergan	Herceptin	Trastuzumab	Roche	2019.06	o	5th Herceptin biosimilar to get FDA approval. 2019 July, first to enter the US market
2019-06-28	Zirabev	Pfizer	Avastin	Bevacizumab	Genetech	2019.07	o	2019 Dec, 2nd Avastin biosimilar to enter the US market
2019-07-23	Rexience	Pfizer	Rituxan	Rituximab	Roche	2016.09	o	2020 Jan, 2nd Rituxan biosimilar released on the market
2019-07-23	Imraldi	Samsung Bioepis	Humira	Adalimumab	AbbVie	2016.12	x	2023 June, 3rd Humira biosimilar to be released (scheduled)
2019-11-05	Ziextenzo	Sandoz	Neulasts	Pegfilgrastim	Amgen	2015.1	o	2019 Nov, 3rd Neulasts biosimilar released
2019-11-01	Abrillada	Pfizer	Humira	Adalimumab	AbbVie	2016.12	x	2023 Nov, 5th Humira biosimilar to be released (scheduled)
2019-12-01	Avsola	Amgen	Remicade	Infliximab	J&J	2018.09	x	4th Remicade biosimilar to get approved. No intention to enter the US market

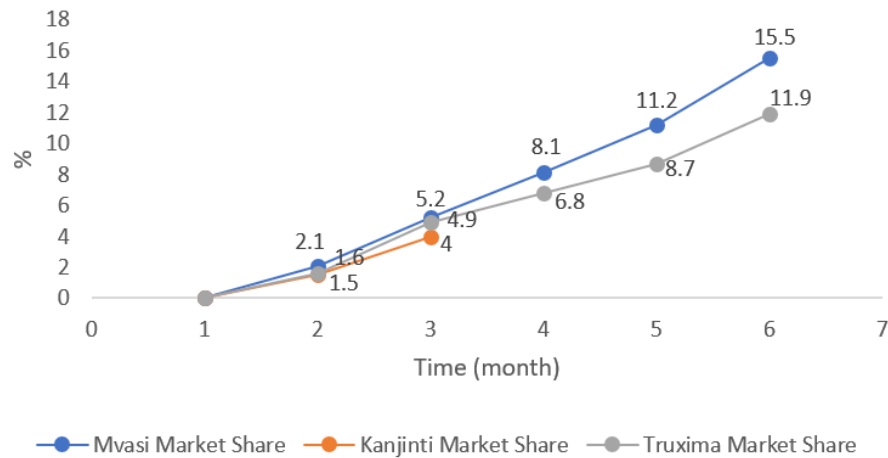
Source: EvaluatePharma

Biosimilars Approval and Market Status in the US



Source: EvaluatePharama

Mvasi, Kanjinti, Truxima Market Share After the Release



Source: EvaluatePharama

Compliance Notice

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- As of February 27, 2020 the writer (Joon Yeon Kim) do not hold any shares of the company mentioned in this paper.

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