Analysis of Factors Influencing Originator U.S. Market Share Following Biosimilar Competition

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Introduction

Biosimilars are biological agents that are analogous to an originator biological therapy (designated as the reference product) that has already been approved by the FDA. Biosimilars are often available at a lower cost than reference products as they seek to gain preferred or advantaged access on health plan formularies to drive uptake. As more biosimilars gain FDA approval, it is important to understand the factors that impact biosimilar utilization.

Objective

This study aims to quantify the relative impact of factors that may influence originator market share with biosimilar competition in the US market.

Methods

A multivariate linear regression analysis included 8 originators with commercially available biosimilars:

Reference Product (Originator)							
Neupogen* (filgrastim)	**Remicade** (infliximab)	**Neulasta** (pegfilgrastim)	**Epogen** (epoetin alfa)	**Herceptin** (trastuzumab)	**Avastin*** (bevacizumab)	**Rituxan** (rituximab)	**Lantus** (insulin glargine)
Biosimilar Product(s) Manufacturer Launch date (earliest to most recent)							
Zarxio Sandoz Sep. 2015	**Inflectra** Pfizer Nov. 2016	**Fulphila** Viatris Jul. 2018	**Retacrit** Pfizer Nov. 2018	**Kanjinti** Amgen Jul. 2019	**Mvasi** Amgen Jul. 2019	**Truxima** Teva Nov. 2019	**Semglee** Viatris Aug. 2020
Nivestym Pfizer Oct. 2018	**Renflexis** Organon Jul. 2017	**Udenyca** Coherus Jan. 2019		**Ogrivi** Viatris Dec. 2019	**Zirabev** Pfizer Jan. 2020	**Ruxience** Pfizer Feb. 2020	
Releuko Amneal Nov. 2022	**Avsola** Amgen Jul. 2020	**Ziextenzo** Sandoz Dec. 2019		**Trazimera** Pfizer Feb. 2020	**Almysys** Amneal Oct. 2022	**Riabni** Amgen Jan. 2021	
		Nyvepria Pfizer Dec. 2020		**Herzuma** Teva Mar. 2020			
		Fylnetra Amneal May 2022		**Ontruzant** Organon May 2020			

Table 1. Originators and their associated biosimilar(s), and the respective launch times for biosimilar(s)
*Originators with orphan drug designations

Hypothesized predictor variables included:

- Aggregate biosimilar market share relative to each originator
- Number of biosimilar competitors
- Duration of biosimilar competition
- Price differentials between originator and biosimilar(s)
- Originator orphan designation
- Degree of payer management

An analysis of 18 health plans' formulary documents as of 1/1/22 was conducted to identify step therapy requirements for each originator through their respective biosimilar(s). Market share and model inputs were captured from FDA, NORD, Drugs.com, and other publicly available sources. Analyses were performed using the SAS statistical package and used a significance level of 0.05.

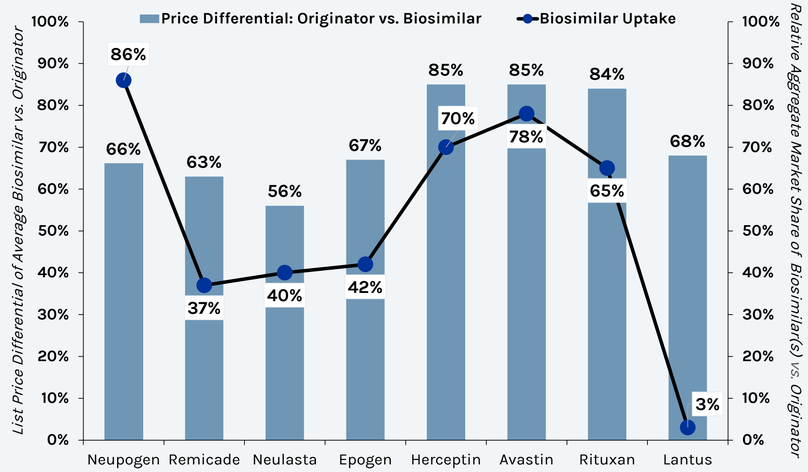

Figure 1: Originator products (by date of earliest biosimilar approval) and WAC Differential of Average Biosimilar Price

Model Type	N	P-Value	R^2	Adjusted-R^2
Model Including Orphan Originators	8	0.508	0.581	0.02
Model Excluding Orphan Originators	6	0.293	0.961	0.8043

Table 2. Statistical analysis of multivariate linear regression

Model Type	Individual Regressions	P-Value	R^2	Adjusted-R^2
Model Excluding Orphan Originators	**Price**	0.005	0.885	0.856
	Price and # of Biosimilar(s) Competitors	0.024	0.917	0.862
	Price and Degree of Payer Management	0.036	0.891	0.818
	Price and Duration of Biosimilar Competition	0.038	0.887	0.812

Table 3. Statistical analysis of individual regressions

Results

The 6-variable model including all 8 originators resulted in an R^2 of 0.581 (p=0.508). After an exhaustive analysis, no predictor variable achieved statistical significance independently or in any combination. However, when excluding Neupogen and Avastin, the 2 orphan originators, and their biosimilars, the R^2 increased to 0.961 (p=0.292). The adjusted R^2 for this model was 0.804, meaning 80.4% of the variability in market share relative to each originator could be explained by price differentials, duration of biosimilar competitors, and payer management while adjusting for each other respectively.

Further, this model resulted in a statistically significant relationship between price differentials and market share (p=0.005). This model also displayed significant results with similar R^2 values in other scenarios, each with the inclusion of a single additional predictor variable alongside price differential. When price differential and number of biosimilar competitors were analyzed in a combined regression, the adjusted R^2 value increased slightly (from 0.856 to 0.862). Although the adjusted R^2 decreased when price was analyzed along with payer management (from 0.856 to 0.818) or duration of competition (from 0.856 to 0.812), the results were also significant, suggesting price as the most impactful factor.

Conclusion

The multivariate regression including the predictor variables better applies to non-orphan originators than orphan originators. Price differential between originator and biosimilar(s) is the only statistically significant predictor variable for biosimilar market share across all regression variations. Although price differential is the main predictor, it is likely that other factors, such as number of biosimilar competitor(s), time since biosimilar launch, and step therapy requirements partially influence biosimilar market share and/or biosimilar pricing decisions. Despite low p-values and high R^2 values, results are limited by the low sample size and lack of access to confidential net prices; only WAC prices were considered. However, the model suggests that price is a significant predictor of biosimilar market share at the list price level.

Future Implications

Based on this research, price differential is the greatest predictor of biosimilar market share; however, amongst a large sample size, it is likely that other variables affect or are affected by price. The number of biosimilar competitors and duration of biosimilar competition likely affect biosimilar pricing decisions. Moreover, these variables and price likely influence payer management decisions. The evaluation of these models should be continuously iterated upon commercialization of new products.

References

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