

Evaluating Various Predictors Suspected of Influencing Biosimilar Market Share in the U.S.

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OBJECTIVES

Biosimilar products, which are derived from an originator biological molecule, have had a significant impact on various therapeutic areas. With rapidly emerging therapies, examining the impact of biosimilar pricing and access is critical for understanding the complexities of the healthcare system.

Biosimilars are often available at a lower cost to their reference product, seeking to gain preferred access on health plan formularies to drive market share. However, originator manufacturers typically engage in contracting to provide discounts and rebates in an effort to defend market share from biosimilar competition. Following an assessment of variables that influence originator market share, we sought to examine how predictors influence individual biosimilar market share.

METHODS

To evaluate the impact of predictor variables on individual biosimilar market share, the multivariate regression model developed in 2022 was utilized. The analysis included 26 commercially available biosimilars and their 10 respective originators. Variables included aggregate biosimilar market share relative to molecule volume, number of biosimilar competitors, duration of biosimilar competition, WAC differentials to the originator, and payer management. An analysis of 15 health plans' formulary documents as of 12/1/23 was conducted to identify step therapy requirements for each product. Market share and model inputs were captured from FDA, NORD, IQVIA Biosimilar Report, Drugs.com, and other publicly available sources. The significance level was $\alpha=0.05$.

RESULTS

The 6-variable model including all 26 products was statistically significant with an R^2 of 0.524 ($p=0.003$). After adjusting for all variables in the model, duration of biosimilar competition and payer management were the only statistically significant predictors of market share ($p=0.011$ for each). An increase in 0.07 days and a decrease in ~3 fewer steps cumulatively across the 15 plans results in an increase of 1% of aggregate biosimilar market share. The adjusted- R^2 for this model indicates that about 43.3% of the variability in biosimilar market share was accounted for by the combination of other predictor variables included.

Output of ISPOR 2024 Model			
Model Type	Variable	Parameter Estimates	P-Value
Model Including All Biosimilars	Price Differential Between Originator & Biosimilar(s)	0.104	0.473
	Duration of Biosimilar Competition (Month)	0.003	0.011
	Number of Biosimilar(s)	0.008	0.557
	Payer Management (out of 15 plans)	-0.226	0.011

Table 1. Statistical output of a multivariate regression model from 2024

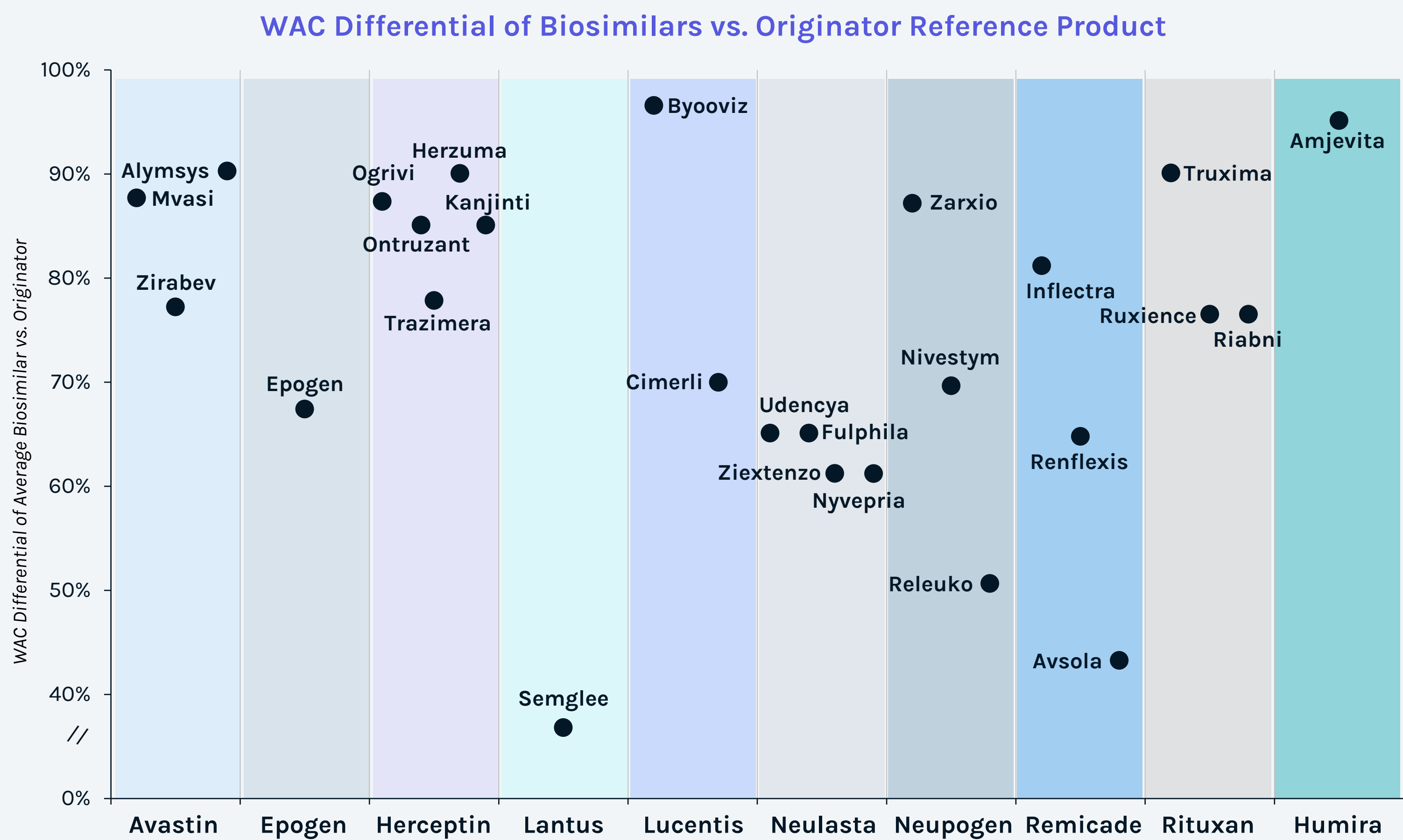


Figure 1. WAC differential of biosimilar vs. originator for individual biosimilar products

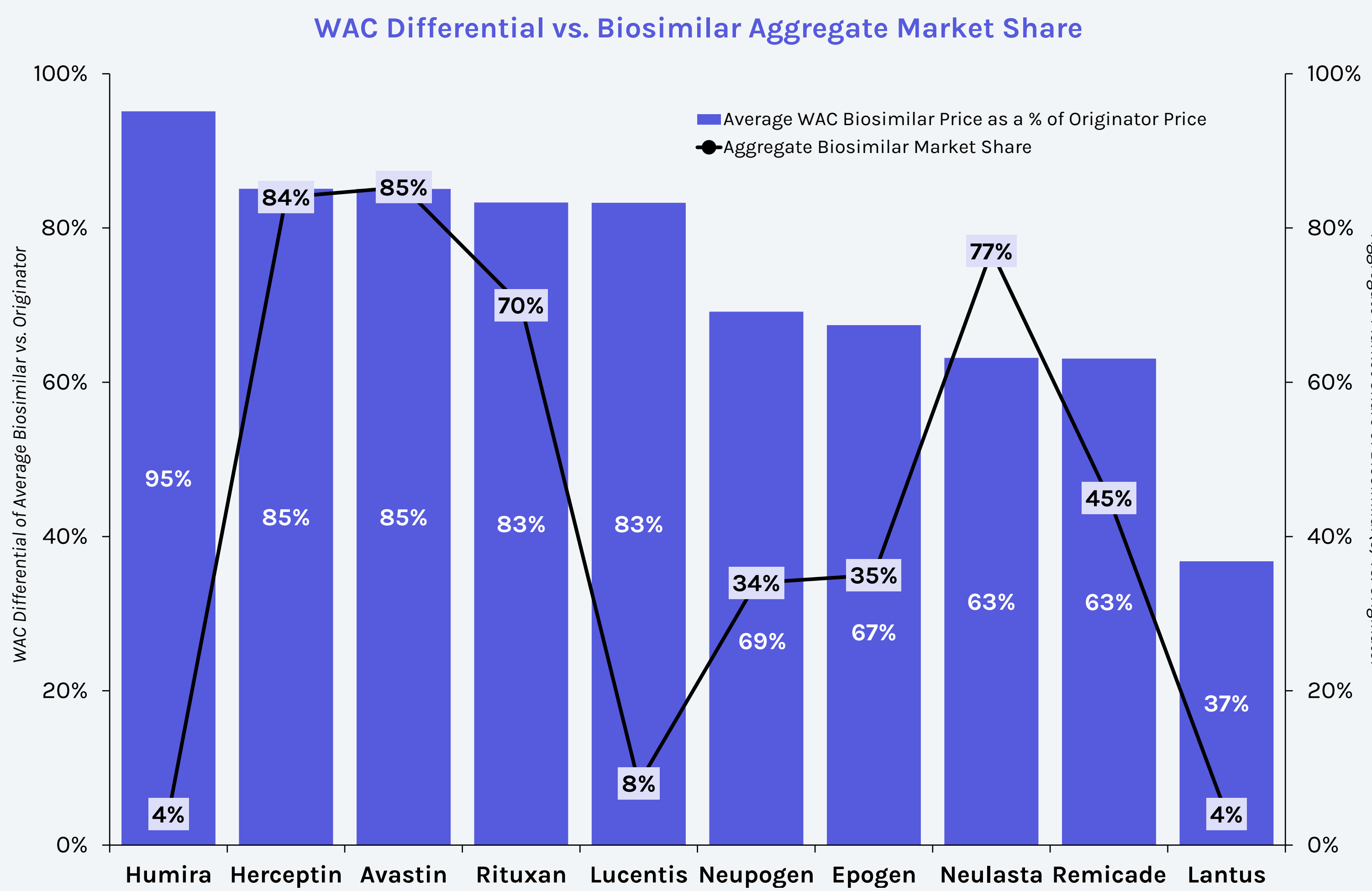


Figure 2. WAC differential by originator and the biosimilar aggregate market share

To further validate the responses, we eliminated the other predictor variables to isolate how payer management and duration of biosimilar competition influenced the overall significance of the model. When WAC differential and number of biosimilar competitors are eliminated, the model achieved increased significance ($p=0.0004$), and both the R^2 and adjusted- R^2 marginally increased (0.498 and 0.454, respectively). These findings underscore the pivotal roles of payer management and the duration of biosimilar competition as the primary drivers influencing aggregate market share.

Output of ISPOR 2024 Model			
Model Type	Variable	Parameter Estimates	P-Value
Model Including All Biosimilars	Duration of Biosimilar Competition (Month)	0.003	0.008
	Payer Management (out of 15 plans)	-0.2134	0.009

Table 2. Statistical output of a multivariate regression model from 2024

CONCLUSIONS

Only duration of competition and payer management are significant predictors of biosimilar market share in the model. The lack of significance of price differential as a major predictor of uptake may be explained because payer management, which is often guided by confidential contractual agreements (e.g., net price discounts or rebates), was more influential on market share predictions. While WAC differential and the number of competitors did not attain statistical significance when adjusting for the other variables in the model, they likely demonstrate an indirect influence on payer management dynamics. The lack of significance of price differential as a major predictor of uptake may be explained by the use of list price rather than net price, which is likely a stronger predictor of access and subsequent market share as it includes discounts and rebates to payers. Inclusion of net price within the model is likely to improve the accuracy of predicting biosimilar market share. Payer management serves as a surrogate for estimating net price, but originator products may be able to maintain premiums to biosimilars as payers wish to avoid switching costs, administrative burden and the risk associated with some patients not switching. This dynamic poses a challenge to potential cost savings by favoring an originator product. Although not all variables demonstrated statistical significance, it is likely other predictor variables influenced biosimilar aggregate market share.

FUTURE IMPLICATIONS

As more biosimilar products are commercialized, understanding the factors that influence aggregate market share is crucial to creating strategies that optimize commercial opportunity for a product expected to lose exclusivity. Given the typical lower-cost of biosimilars, payers may look to further limit originators in preference of the biosimilar alternative(s). It will be important to monitor how biosimilar aggregate market share changes due to suspected price erosion following an originator's loss of exclusivity.

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α = Alpha
 β = Parameter Estimates

