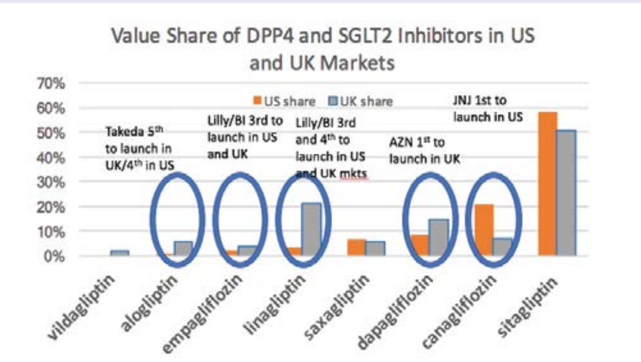
SGLT2 Inhibitors – Disrupting the Type 2 Market in 2017?

Introduction

There are few primary care categories as dynamic as diabetes (Type 1 and 2); not only is the category forecast to grow at 6.8% globally through to 2022 as more patients are diagnosed but it is likely to become the second largest category after oncology[1]. More intriguing is that the players in this therapeutic area are relatively few in number and yet their competitive position in key geographies belies their marketing strength in other markets or treatment categories. The comparison between US and UK markets is particularly instructive. While there are different access and reimbursement issues in each market, with different launch dates, the UK market shares differ so markedly from those in the US they raise serious questions about marketing strategies and capabilities.(see Figure showing comparison of US and UK shares). The cardiovascular benefits of Boehringer Ingelheim/Lilly's *empagliflozin* add an extra competitive dynamic to this market and the recent endorsement by the American Diabetes Association, as well as the label changes at FDA, could have dramatic effects in the wider Type 2 marketplace.

Figure 1: A comparison of value share of DPP4 and SGLT2 inhibitors in the US and UK markets



Source: PCA data from http://www.nhsbsa.nhs.uk/PrescriptionServices/3494.asp , Earnings reports for individual companies.

It is easy to dismiss these market share phenomena as simply reflecting differential geographic marketing (and market access) strengths and launch date order. However, there is little likelihood that the companies involved had forecast such skewed sales performances between markets and so shareholders and management alike are entitled to ask why these deficiencies have not been addressed. Why has Janssen's *canagliflozin* failed to take a reasonable share ex-US; why has AZN's *dapagliflozin* not made greater inroads in the US; why is AZN's *saxagliptin* a distant third in the DPP-4 market and why is Takeda's *alogliptin* set to overtake AZN's *saxagliptin* in the latter's home market, despite a much later launch? These questions remain largely unanswered and suggest that future forecasts, including up to $150bn of cumulative global sales to 2022, remain in doubt as to their company attribution.

A UK Perspective

It may be argued that positioning two oral drugs for Type 2 diabetes has confounded a clear marketing strategy; AstraZeneca have both *saxagliptin* and *dapagliflozin*. However, there was a three year gap between the launch of *saxagliptin* and *dapaglifozin*, so that argument is weak. More compelling is the outcome of the SAVOR study that showed an increase in hospitalisation for heart failure when comparing *saxagliptin* with the placebo group. This was published in late 2013. However, Takeda's *alogliptin* study, EXAMINE, also published in late 2013 showed a similar tendency. Indeed both *alogliptin* and *saxagliptin* have had FDA label changes as a result of these trials. Despite this Takeda continues to perform really well in the UK as a "tainted" latecomer. Takeda has launched *alogliptin* at a 16-20% discount to the other drugs in the class and this may have overridden safety concerns for price-sensitive customers.

From the outsider's perspective there are two clear outliers in terms of poor performance relative to expectation; AstraZeneca's *saxagliptin* and Janssen's *canagliflozin*.

1. Why is AstraZeneca's *saxagliptin* now in decline and being out-sold three to one by Boehringer's linagliptin and about to be overtaken by Takeda's latecomer, *alogliptin*, in AZ's home market?
2. Why has Janssen's *canagliflozin*, which is the clear market leader in the US, been outsold two to one by AstraZeneca's *dapagliflozin* in the UK and likely to be overtaken by Boehringer's *empagliflozin* in 2017?

Conclusion

There are relatively few primary care categories these days that can still "move the needle" for companies' earnings. However, the Type 2 diabetes category is one such. With the global sales forecast of oral drugs for Type 2 to be in excess of $30bn by 2022 (excluding NovoNordisk and Sanofi, because they are mainly selling biologicals), there is a lot at stake for the handful of public companies involved. Senior management have much to do if they are to understand the forces that drive their sales and earnings. Throwing promotional resources at the problem, without a true understanding of the likely impact on sales is a recipe for significant waste. While high gross margins have allowed this sort of profligacy in the past there can be no excuse at a time when payers are insisting on value for money. 2017 looks like it will bring significant additional competitive pressures to bear on the Type 2 diabetic market, so perhaps a good New Year's resolution would be to ensure that all market analyses are as rigorous as the clinical trials that underpin their regulatory legitimacy.

1 Evaluate Pharma – World Preview 2016, Outlook to 2022

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