

Turn of The Decade: Novel Glp-1's To Emerge as the New Leader in Diabetes Class

<https://marketpublishers.com/r/TBE9A356A00EN.html>

Date: September 2011

Pages: 68

Price: US\$ 2,000.00 (Single User License)

ID: TBE9A356A00EN

Abstracts

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Bydureon – A near term growth driver of the class

Novel delivery platforms and fixed dose combination of GLP-1's + Insulin will drive growth in longer term

This decade of the diabetes therapy class will be marked by the domination of (Glucagon-like Peptide-1) GLP-1 agonist as we expect this class to grow faster than any other class of drugs in the diabetes space. The best in class clinical attributes of GLP-1's (robust HbA1C reduction, reduced hypoglycemia, and significant weight loss) supported by compliance benefit positions it better than its competitor's to make the most of the growth opportunity available in the diabetes market. Due to compliance issues and long term safety concerns, currently the use of GLP-1 is limited prior to insulin and after oral treatment options are exhausted.

The current prescribing pattern in the US and EU is reflective of the same. Non-Compliance which affects about 30% of the type 2 diabetes patients is a major issue and has a bearing on the diabetes treatment and its potential benefit. Innovation efforts are ongoing to enable convenient delivery of GLP-1's. Longer acting versions, Transdermal, oral, nasal, and implants which can deliver once daily or up to once yearly dosing benefit are being explored. These new delivery platforms and formulation techniques in this class will significantly help compliance and will also bring further improvement in the current clinical profile.

There is a need for new treatment options in diabetes as diabetic patients remain

largely uncontrolled and existing treatment options are losing out on safety issues. Reported mean HbA1c in major markets of world remain above the local targets. This reflects need of a treatment options which can offer robust efficacy and compliance; GLP-1's best fit the bill. Thiazolidinedione (TZD) and sulfonylureas do offer solid efficacy benefits, but they are also associated with safety concerns and physicians are looking for alternatives. SGLT2 could have been a potential replacement for TZD's/sulfonylurea, but they are not as efficacious and have also shown association with cancer (bladder and breast) in clinical trials, which raises a red flag on their approvable probability.

With every passing year, the evidence base on the long term safety of GLP-1's is growing and this together with data from ongoing studies (LEADER and EXSCEL) exploring long term safety of GLP-1's, the GLP-1's should climb up in the diabetes treatment algorithm. Once the once weekly versions (Bydureon (EU approved), Syncria, Liraglutide once weekly depot version/semaglutide) are introduced in the market, GLP-1 penetration will increase in early stages, especially in obese patients which comprise 60% of the diabetics. GLP-1's will initially replace sulfonylureas and TZD's, which together comprise 37% of the market.

Fixed dose combinations of Insulin and GLP-1 under development will boost the usage of GLP-1 in combination with insulin, and should emerge as gold standard for the insulin dependent diabetes patients. The combination will help take care of weight gain, better glucose control and hypoglycemia – which are three major issues faced by insulin dependent patients.

There are about 34 GLP-1 pipeline candidates that are being designed for significant enhancement over current marketed GLP-1's. The most advanced pipeline candidates have reported a solid proof of concept data, and promise mega blockbuster potential. A host of companies are working on novel delivery platforms and longer acting versions of existing compounds to override the compliance related issues associated with the current marketed GLP-1's. Besides Lilly, Amylin and Novo Nordisk, Hanmi Pharmaceuticals, Intarcia therapeutics, Zealand Pharma, Transtech pharma, Ascendis Pharma are other companies, which have significant stakes in the GLP-1 class.

In the diabetes space, the emerging market especially represents a major opportunity. The growth in emerging markets is driven by growing diagnosis, insurance penetration improving affordability, improving patent situation and most important of all, the strong marketing efforts of the global pharmaceutical companies.

We forecast \$10b in cumulative peak sales for this class of drugs by the turn of this decade as we see innovation efforts around this class will result in improved compliance, convenient delivery and improved safety profile which should drive GLP-1's evolution to a front line treatment option.

Contents

COMPANIES MENTIONED

Eli-Lilly; Novo Nordisk; Sanofi; GlaxoSmithKline; Pfizer; AstraZeneca; Boehringer Ingelheim; Amylin; Alkermes; Human Genome Science; Zealand Pharma; Intarcia; Hanmi Pharmaceuticals; Prolor Biotech; Ascendis Pharma; PharmaIn; Versartis; CellMed AG; Oramed;

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