

Diabetes: Battle for ascendancy escalates in expanding market – KOL Insight

<https://marketpublishers.com/r/D9AB42674FAEN.html>

Date: July 2013

Pages: 0

Price: US\$ 4,995.00 (Single User License)

ID: D9AB42674FAEN

Abstracts

Diabetes is one of the few disease areas that has retained its market value despite the entry of generics, the rise in drug prices and prevalence of the disease has allowed drug sales to soar to a worldwide value of \$34.1 billion in 2012. While barriers to entry remain high with added scrutiny over cardiovascular and other safety risks, evident by Tresiba's (insulin degludec; Novo Nordisk) recent US failure, the exponential market growth makes diabetes one of the most attractive opportunities in Pharma.

Competition in the major drug segments are intense with Sanofi's basal insulin Lantus (insulin glargine), Novo's prandial insulin NovoRapid/NovoLog (insulin aspart), Merck's DPP-IV Januvia (sitagliptin), and Novo's GLP-1 Victoza (liraglutide) leading the way in their respective classes with best in class efficacy and safety. In addition to these clinical advantages, more convenient administration devices and strong marketing has helped them stand out from the competition.

While Novo Nordisk, Sanofi and Merck look set to protect their franchises with exciting pipeline therapies, Key Opinion Leaders interviewed by FirstWord note that there are a number of unmet needs in diabetes treatment and management. Companies that can address these needs and differentiate their products from existing players will see significant traction in this lucrative indication. This is evident from the successful launches of the novel SGLT-2 inhibitors- Invokana (canagliflozin; Johnson & Johnson/Mitsubishi Tanabe) and Forxiga (dapagliflozin; Bristol-Myers Squibb/AstraZeneca), in the US and EU. In addition, therapies showing significant incremental advances also have potential to usurp market share from the gold standard treatments.

'Therapy Trends: Diabetes' is compiled from exclusive, in-depth interviews with the

world's leading Key Opinion Leaders in diabetes. It identifies and analyses the major factors, advances and trends currently influencing the diabetes treatment landscape. The report focuses on late-stage pipeline products, and how these could modify future Diabetes management.

FirstWord selected the KOLs for this Therapy Trends report based on their level of engagement and influence within the diabetes disease area, and their scientific standing and clinical experience. Our unique KOL scoring system identifies those thought leaders with the greatest insight into how diabetes clinical research will shape the future market.

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About

This report examines the most prominent insights gained from five key opinion leaders (KOLs) from North America and seven KOLs from Europe. Results of FirstWord's research and analysis for KOL Insight: Diabetes identified the following major findings:

- Diabetes market value continues to grow unabated to \$34.1 billion in 2012—The diabetes market is one of the few disease areas that has been largely unaffected by the entry of generic molecules. The rise in obesity, drug prices and disease prevalence has allowed diabetes drug sales to continue to outpace large pharma drug sales. The diabetes market has grown at a compound annual growth rate (CAGR) of 10.0 percent from 2007 to 2012 to reach worldwide sales of \$34.1 billion;
- Lantus fends off competition to remain the number one diabetes therapy – In the future, Novartis' Lantus (insulin glargine) will face competition from biosimilar glargine and Sanofi's own second generation insulin glargine, U300. However, with approval of Novo Nordisk's Tresiba (insulin degludec) delayed in the US due to cardiovascular concerns, Lantus will continue to dominate the basal insulin class due to its convenient dosing and strong efficacy;
- Victoza and Januvia entrenched as leading integrin therapies in largely undifferentiated classes –Although new therapies have entered the glucagon-like peptide-1 (GLP-1) agonist and dipeptidyl peptidase-IV (DPP-IV) inhibitor classes, Novo Nordisk's Victoza (liraglutide) and Merck's Januvia (sitagliptin) continue to hold the leading positions in their respective spaces, with \$1.6 billion and \$4.1 billion in sales worldwide in 2012. There appears to be a lack of clinical distinguishing features that would separate one drug from another in these particular integrin classes. Favourable dosing, market experience, marketing capabilities and easy-to-use devices has helped differentiate therapies;
- Pipeline shows incremental advantages over existing therapies rather than novelty –To offset the disadvantage of not being first to market, new pipeline therapies entering the treatment algorithm will have to meet most of the current unmet needs to become a gold standard treatment. However, pipeline therapies offer only slight advantages over existing therapies. The most exciting

therapies include Sanofi's U300, a Phase III basal insulin offering "peak-less" delivery of insulin, and NovoNordisk's IDegLira (liraglutide + insulin degludec) a basal insulin/GLP-1 fixeddose combination that has demonstrated strong early efficacy results;

- Closed loop systems and vaccines will be the next game changers –One of the most welcomed developments KOLs look to is the eventual availability of a closed loop system acting as an artificial pancreas. There are a number of companies with promising improvements in pump therapy and sensor technologies. Another area of excitement comes from recent data regarding a reverse DNA vaccine, TOL-3021, which stops the patient's own immune system from attacking their beta cells. Replication of successful proof of concept results for a longer duration and larger scale is highly anticipated.

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