

Allergy vs. Hypoglycemia: GlucaPen™ Potential in the US

The emergency glucagon kits (EGKs) currently marketed by Eli Lilly and Novo Nordisk for the treatment of severe hypoglycemia (SH) generated combined annual revenues of approximately \$70mm in the United States in 2008. We believe that the market is significantly underserved by the two companies, with little to no promotional effort and products that are neither intuitive nor user-friendly. GlucaPen™ provides superior technology, ease of use, greatly improved safety features, and will be backed by targeted educational and promotional support. Efforts will be focused on raising the awareness level of the risks of hypoglycemia, promoting GlucaPen™ purchases as insurance against the risks of SH, improving the prescribing practices of physicians for their diabetic patients, and emphasizing the potential cost savings to the US health care system.

GlucaPen™ Potential

The following table illustrates our view of the potential US market for SH in 2013:

Market Segment			Units (000's)
Type 1 patients	1.4mm*	1.15** episodes/year	1,610
Insulin-using Type 2 patients	5.7mm	0.5 episodes/year	2,843
Type 1 patients buying 2 units/year	20%		280
Type 2 patients buying 2 units/year	6%		341
Public schools	120K	2 units purchased/year	240
Ambulances/fire depts./EMS units	41K	3units purchased/year	123
Total market potential			5,437

* JDRF's web site indicates there may be as many as 3 million Type 1s

(http://www.jdrf.org/index.cfm?fuseaction=home.viewPage&page_id=14AF69BC-BE51-42DA-B1B41955029FBC7F)

** The episode rate may be as high as 2.7 SH events per year. Jorgensen, HV, Pedersen-Bjergaard U, Rasmussen, AK and Borch-Johnsen K: The impact of severe hypoglycemia and impaired awareness of severe hypoglycemia on relatives of patients with type 1 diabetes. *Diabetes Care* 26:1106-1109, 2003

Comparison of the Severe Allergic Reactions and Severe Hypoglycemia markets

To provide further support for our sales estimates, we look to the EpiPen® business as a surrogate. EpiPen® is an auto-injector pen, marketed by Dey Laboratories, a Mylan, Inc. subsidiary, that delivers a dose of epinephrine for the emergency treatment of severe allergic (anaphylactic) reactions (SAR). Prior to EpiPen®'s introduction, emergency epinephrine was administered via a syringe-ampoule kit, very similar in functionality to the syringe-vial kits for administering emergency glucagon.

Although precise data is sparse and comparisons between two different disease states is less than perfect, the following table provides information about the markets for SAR and hypoglycemia. It is intended to provide a basis for better understanding the true opportunity for GlucaPen™ after comparing EpiPen® and EGK statistics.

	Allergic Reactions	Hypoglycemia
Number of deaths per year (US)	150-200 ¹	2854-9278 ²
Number of ER visits per year (US)	30,000 ³	50,000 ⁴
Percentage of EpiPens®/EGKs used per year	10% ⁵	10-25% ⁸
Number of units sold in US (2008)	1.9 ¹³ million	0.9 ¹⁴ million
Unit growth (CAGR)	11% (10 years) ¹⁵	11% (5 years) ¹⁴
Promotional effort	Yes	No
Number of hospital admissions	9,500 ⁶	351,000+ ⁹
Incidence of US population	1-2% ⁷	1.23-2.76 ¹¹
US sales (2009)	~\$233 ¹³ mm	~\$80 ¹⁴ mm
# of units per patient	2-6 ¹⁰	.20 ¹²

References:

- 1 - <http://www.webmd.com/allergies/news/20100326/kids-with-food-allergies-may-need-two-epipens>
- 2- <http://diabetes.diabetesjournals.org/content/57/12/3169.full>;
<http://www.diabeteshealth.com/read/1997/07/01/878/hypoglycemia---what-every-person-on-insulin-should-know/>;
<http://www.healingwithnutrition.com/ddisease/diabetes/diabetes.html> (71,372 x 4-13%)
- 3- <http://www.fda.gov/food/resourcesforyou/Consumers/ucm079311.htm>
- 4- <http://www.solvingdiabetes.org/2010/05/10/prevention-of-hypoglycemia/>
- 5- <http://webcache.googleusercontent.com/search?q=cache:5fndLCtoC84J:anaphylaxistalk.com/viewtopic.php%3Ff%3D12%26t%3D2141+how+many+epipens+were+prescribed+in+2008&cd=1&hl=en&ct=clnk&gl=us&client=firefox-a>
- 6- <http://www.cdc.gov/nchs/data/databriefs/db10.htm>
- 7- <http://www.ncbi.nlm.nih.gov/pubmed/18596588>
- 8- No available data
- 9- Calculated from Kaiser Admission Data:
<http://www.statehealthfacts.org/comparetable.jsp?yr=63&typ=1&ind=386&cat=8&sub=94&sortc=1&o=a> and NIH Report (Chapter 13) table 13.5: <http://diabetes.niddk.nih.gov/dm/pubs/america/pdf/chapter13.pdf> using (0.01 vs. 0.09)
- 10- <http://anaphylaxistalk.com/viewtopic.php?f=2&t=1868&start=0> (Anecdotal like the E-Kit use)
- 11- <http://www.ncbi.nlm.nih.gov/pubmed/9250229>
- 12 – 900,000 kits sold/4,453,000 T1 + T2. This represents a significant upside opportunity in unit sales
- 13 – IMS data for 2009
- 14 – IMS data for 2008; 2009 estimated using historical growth rates
- 15 - Presentation by Mylan at JPMorgan January 2009

Summary

- 1) The number of hospital admissions, ER visits and deaths is significantly greater for SH than SAR.
- 2) The opportunity for multiple unit purchases for a pen in SH is at least equivalent to SAR.
- 3) The potential cost savings from treating SH far exceed that of SAR.
- 4) The awareness and promotion of SAR/EpiPen® is dramatically higher than SH/EGKs, presenting a significant upside opportunity for growth in GlucaPen™.
- 5) Although these two markets are similar in many respects, the hypoglycemia market appears to present an opportunity equal to or greater than SAR.

Footnote on ex-US markets: There is a large disparity in price between epinephrine ampoules and EpiPen® (~40 fold). The fact that EGKs sell for a third or less of the US price in major markets outside North America should not discount the magnitude of the opportunity in these markets. Similar to EpiPen®, no one will want an EGK once GlucaPen™ is introduced. Supporting this contention is that fact that EpiPen® prices in a number of major Ex-US markets exceed those of the US.