



73 Highland Road, COVENTRY, West Midlands, CV5 6GS, United Kingdom
Tel: +44 (0)24 7671 3482 Fax: +44 (0)24 7671 3115 www.biophoenix.com
Directors: S Bogdanovic (Managing), B Langlands, A Atkins, B Carless
Registered in England No 3584084 VAT No 927760790

Monday, 7 July 2008

FOR IMMEDIATE RELEASE

Cholesterol-lowering market "full of potential" according to new report.

COVENTRY, UK, 7 July 2008 / -- Drugs to control abnormal blood levels of cholesterol and other fats, collectively known as dyslipidemia, are prescribed to more than 30 million at-risk people worldwide to prevent heart attacks and strokes. Although the dyslipidemia market is still the second largest therapy area worldwide (second only to oncology), this market is currently rather sluggish following the loss of patent protection for two widely used medicines. However, according to a report published today by Biophoenix, the current situation is far from gloomy. Biophoenix forecasts that, if present trends continue, the dyslipidemia market, dominated by statins, will grow slowly from \$36 billion in 2007 to \$42 billion in 2012. Crucially, the report finds that the dyslipidemia market is characterised by underutilization and that growth could be increased substantially without making any fresh scientific breakthroughs or developing any new drugs. In the slightly longer term the market is poised for transformation with the advent of novel combination products and biopharmaceuticals. The report mentions over 120 companies and identifies more than 150 compounds in commercial development.

"In an era of diminishing R&D pipelines, drug companies need to make the best use of the market opportunities that they do have", says study co-author Dr Beata Langlands. "Although there are a number of interesting and novel lipid-lowering drugs in development, which are thoroughly discussed in the report, few are likely to make it onto the market before 2011 or 2012". The so-called CETP inhibitors, which were front-runners prior to publication of a clinical trial called ILLUMINATE, have suffered a setback following the withdrawal of the lead agent, torcetrapib.

Statins dominate the dyslipidemia market. "Statins do a great job of lowering LDL ('bad') cholesterol", says Dr Langlands, "but they don't treat other lipid risk factors such as low HDL ('good') cholesterol or high triglycerides, which are often present as well, and may be overlooked altogether by prescribers". Even among people with high LDL cholesterol, most are undertreated, or not treated at all. Many stop taking their medicines after a few months. Moreover, according to the "inverse care law", those patients at highest risk, and most in need of intensive therapy, are least likely to receive it. Examples of high-risk patient categories include hypertensives, persons with kidney disease, the elderly, the obese, diabetics, rheumatoid arthritis sufferers, and people with AIDS. Women in general tend to be undertreated compared with men. These groups are clinically and commercially important targets.

The size of the treatment-eligible patient population, currently over 36 million (18% of the adult population) in the US alone, continues to increase, driven by spiralling rates of obesity, type II diabetes, and the related metabolic syndrome. Fewer than half of these currently receive lipid-controlling medication. The pharma industry has a part to play in improving drug utilization through more intensive education and promotion. Merck's success with Zetia (ezetimibe), particularly in the US, and before the disappointing ENHANCE trial results were published, shows what can be achieved. The adoption by medical authorities of more aggressive lipid targets increases the opportunity for monotherapy with patented statins (which are more powerful than their generic alternatives) and, more especially, for combination therapies.

In its conservative market forecast, Biophoenix anticipates that, as a proportion of the market, statins will fall from 67% in 2007 to 44% in 2012; most of this decline will occur towards the end of the forecast period as Pfizer's Lipitor (atorvastatin), still the world's top-selling medicine, loses patent protection. "Much of the growth in the market is coming from non-statin segments; ezetimibe, niacin, fibrates, and even prescription omega-3 esters", observes study co-author Dr Sreten Bogdanovic. Among the branded statins, only AstraZeneca's Crestor (rosuvastatin) is gaining ground, buoyed to some extent by the expectation of good news from its JUPITER study later this year.

The most important known non-LDL risk factor is low HDL, and the drug best able to raise it, in the absence of the CETP inhibitors, is niacin. This agent is famously hard to tolerate, although current extended release (ER) formulations are acceptable to most patients. The current brand leader in ER niacin is Abbott, with Niaspan, although Merck & Co has a similar product (Tredaptive) approved in Europe. Biophoenix forecasts that sales of niacin and niacin-based combinations will continue to grow at almost 19% per year over the next five years, although sales could be much higher, depending on how intensively these products are promoted.

Even optimal statin therapy reduces risk by only about a third, and hence fails to prevent most heart attacks. "The logical way to manage multiple risk factors is with multiple interventions using single- or multi-pill combination therapies", says Dr Bogdanovic. "There is some intriguing evidence, from small-scale trials such as HATS and FATS, that combination treatments, which raise HDL as well as lowering LDL and triglycerides, can reduce the risk of a repeat heart attack by up to 90%, and may even be able to reverse heart disease". Large trials of Niaspan and Tredaptive are presently under way to resolve this issue. The availability of generic statins now makes it easy to develop effective combination treatments to target multiple lipid abnormalities. Previously, licensing would have been required.

NOTES FOR EDITORS

About the report

Dyslipidemia: Opportunities in Cardiovascular Risk Reduction is a 200-page study of scientific and commercial trends and opportunities in the worldwide lipid-lowering market, based on extensive primary and secondary research, and conducted by Biophoenix' principal executives, Drs Sreten Bogdanovic and Beata Langlands.

Table of Contents

Executive Summary
Chapter 1 Introduction
Chapter 2 Biomarkers and Surrogate Endpoints in Atherosclerosis
Chapter 3 Improving Mainstay Therapies
Chapter 4 Focus on HDL
Chapter 5 Other lipid modulators in development
Chapter 6 Market outlook
Chapter 7 Market potential
Appendices

The report costs \$3,000 / £1,500 / Euro1,920 (PDF or CHM). Further details can be obtained from Biophoenix' website at www.biophoenix.com/reports/lipids.

About Biophoenix

Biophoenix is a biomedical consultancy based in the heart of England, which was founded by Dr Sreten Bogdanovic and Dr Beata Langlands. Established with support from the predecessor to the UK's Department for Business, Enterprise and Regulatory Reform (BERR) in 1994, Biophoenix

provides detailed, accurate, market and technical information to support decision-making by biotechnology-based enterprises in the healthcare industry. In doing so, Biophoenix relies on its comprehensive in-house bioindustry database and a wide network of contacts. Biophoenix has researched and written over 50 in-depth management/market reports which have been published by clients such as Frost & Sullivan, the London *Financial Times*, *Scrip*, *Clinica*, and Datamonitor. Biophoenix also audits biotechnology-based enterprises with regard to the risk of intellectual property litigation on behalf of several Lloyds of London insurers. Further information is available on the internet at www.biophoenix.com.

Contact

Dr Sreten Bogdanovic
(Coventry Office)
+44 (0)2476 713482

- or -

Dr Beata Langlands
(Kenilworth Office)
+44 (0)1926 864223

#####