

## Not enough done to fight alcoholism

A shift in disease perception is required to fully utilise available drug treatments for alcoholism.

Enjoying a pint at your local, or an evening of drinking and dancing in a nightclub is seemingly as much a part of the fabric of British society as queuing or supporting the national football team, as it is in many countries throughout the world. However, while the majority of people are able to consume alcohol in moderation, in a proportion of the population alcohol use can develop into alcoholism, or alcohol dependence.

Estimated to be worth just \$86 million 2006\*\*, according to a new report\* from independent market analysts Datamonitor, the alcohol dependence pharmaceutical market is set to grow to \$304 million by 2016\*\*, driven by the launch of two pipeline opioid antagonists and the continued uptake of Alkermes and Cephalon's injectable opioid antagonist Vivitrol (naltrexone). However, for substantial long-term success in drug treatment for alcohol dependence, a shift in disease perception is required.

### **Alcohol dependence is often under-diagnosed and under-treated**

Alcoholism is a chronic, progressive and potentially fatal disease characterised by the frequent drinking of excessive amounts of alcohol and the inability to curb drinking. It is the third leading cause of preventable death in the US (following smoking and obesity) (1) and represents a major economic burden to society in terms of the healthcare costs of treating resultant illnesses, lost work days and social problems.

Datamonitor estimates that alcohol dependence affects almost 20 million individuals across the seven major markets (7MM)\*\*, Datamonitor central nervous system (CNS) analyst Charlotte Mackey says. "Although the dangers of alcoholism are widely known and despite the availability of screening tools, Datamonitor's research suggests that this condition is under-diagnosed and under-treated in the clinical setting."

A key reason for this is a lack of resources in terms of treatment facilities, trained physicians and funding (Key opinion leaders interviewed by Datamonitor support this. They concur that greater provision of resources and funding represents the largest unmet need in the treatment of alcohol dependence.

Other potential reasons for under-diagnosis include the social stigma associated with alcoholism preventing individuals from seeking treatment, denial that a serious problem exists and the perception among physicians that it is not treatable, Mackey says. "There is considerable room for improvement in the diagnosis and management of alcohol dependence, and the reported lack of resources indicates that changes are required in policy, which in practice, places an emphasis on physician training.

"Widespread education efforts are also required to inform the public of the available treatment options," she says.

### **Limited range of drug treatments leaves market opportunity for new therapies**

Despite the high prevalence of alcohol dependence, the range of available prescription drug treatments is limited to just four products, which together garnered sales of a modest \$86 million across the 7MM in 2006. To put this in perspective; depression medications achieved 7MM sales worth \$11.8 billion in 2006.

As well as being few of them, available medications offer limited efficacy, with many patients relapsing back to drinking within the first year of beginning treatment. Datamonitor believes there remains substantial opportunity for new drugs which are able to improve upon the effectiveness of Vivitrol (naltrexone, Alkermes/Cephalon), a once-monthly intramuscular injection and the most recent drug to enter the alcohol dependence market in 2006.

Vivitrol works by blocking opiate receptors in the brain that reduces the euphoric feeling or 'high' associated with alcohol use. Furthermore, because of the reportedly poor medication compliance rate among alcohol dependent patients, it is expected that future drugs that possess the potential to improve patient compliance can expect to receive a strong uptake.

Mackey says, "In view of the huge health and social impacts of alcohol dependence, the introduction of a highly efficacious and safe treatment could lead to huge savings for individuals, businesses and the economy."

### **Drugs in development for alcohol dependence are lacking in innovation**

Of the small number of drugs currently in clinical development for the treatment of alcohol dependence, the majority are of the opioid antagonist class; the same class as two of the presently available treatment options (ReVia (oral naltrexone, Barr Pharmaceuticals) and Vivitrol)).

Datamonitor predicts the launch of two opioid antagonists in 2011; BioTie's nalmefene and Elbion's Naltrexone. Nalmefene is currently the most encouraging drug in late-stage development and its anticipated lack of requirement for alcohol abstinence prior to treatment and 'as-needed' dosing regimen will make the drug an attractive treatment option for patients. However, based on mediocre clinical data to date, the drug is not expected to overtake Vivitrol's prescription sales and Datamonitor forecasts nalmefene to achieve sales of \$75m by 2016 in the US and 5EU markets.

By comparison, Elbion is expected to experience difficulty in distinguishing Naltrexone depot injection, from Vivitrol, and for this reason, the drug is forecast to garner US and 5EU combined sales of just \$40m by 2016.

The relatively low uptake of currently marketed alcohol dependence products means that strong marketing campaigns that disseminate persuasive information on the benefits of drug treatment will be vital to future drugs entering this market in order to ensure a strong uptake.

### **A shift in disease perception is needed if the alcohol dependence market is to grow substantially in the long-term**

The present state of under-diagnosis and treatment of alcohol dependence and lack of innovation among drugs in development may be attributable to a limited acceptance of drug treatment for alcohol dependence in comparison to the wider social acceptance of other psychiatric medications. It is also possible to speculate that the relatively low sales of alcohol dependence drug therapies results from a prevailing view that the disorder is a behavioural problem, as opposed to a medication condition. This view is supported by the fact that psychosocial therapy continues to play a key role in the treatment of alcohol dependence.

Key opinion leaders interviewed by Datamonitor believe the diminutive size of the market resembles the state of the depression market over 20 years ago, before the launch of Prozac (fluoxetine), which led to a

shift in society's perception of depression. Datamonitor believes that in order for substantial growth to occur in the alcohol dependence market, a similar shift in disease perception is needed, Ms Mackey says.

“A movement away from the public perception that alcohol is a behavioural disorder towards being regarded as a treatable medical condition is needed.

“Such a shift, brought about by a highly efficacious drug would serve to increase awareness of pharmaceutical treatment options and substantially expand the market,” she says.

*\*Pipeline Insight: Substance Dependence – Part II: Alcohol*

**\*\*Seven major markets: UK, US, France, Germany, Italy, Japan and Spain, MIDAS Sales Data, IMS Health July 2007.**

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