

**Investment Brief for
The Fourth Class of Drugs to Treat Heart
Failure**

**NSW
AREA HEALTH
SERVICES**

Office of Commercialisation

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The Fourth Class of Drugs to Treat Heart Failure

Summary

A new class of drugs to treat heart failure has been identified. The drugs are aimed at restoring heart function after heart failure. Drugs have already been trialled (unsuccessfully) for other diseases and were shown to have no negative cardiovascular effects.

Market

Heart failure affects about 2% of the population with a five year mortality rate of 50%. The estimated number of patients is approximately 14mill in the western world which gives a market size of US\$15bill.

Benefits

This new class of drugs provides for a new strategy to treat heart failure which will complement and enhance existing treatments.

The Opportunity

While flying over Fiji, Professor Helge H Rasmussen and Dr Henning Bundgaard from Royal North Shore Hospital and the University of Sydney developed a major paradigm shift for clinical treatment of patients with heart failure. Extensive in vitro studies followed, supporting the new paradigm, and a pivotal study in sheep later confirmed it. They had discovered a new class of drugs that could be used in the treatment of heart failure.

The drugs studied by Rasmussen and Bundgaard belong to a group of orally active drugs of different chemical composition but with one particular biological property in common. Drugs that possess this property have been developed by several pharmaceutical companies for other purposes for which they have not been effective. Those that have reached phase II clinical trials in humans have reported no cardiovascular side effects. This new class of drugs will improve the pumping action of the failing heart and ameliorate the profound social impact that heart failure has on patients and families.

Value Proposition

Heart failure (HF) occurs with a prevalence of about 2% in industrialised countries. It is characterised by a reduced pumping capacity of the heart and hence reduced perfusion of the body. Despite advances in treatment the 5-year mortality remains distressingly high at ~50%, and in some subgroups even higher. This is a new class of drugs that will be used to treat heart failure, enabling the heart to pump more strongly, restoring energy and improving survival.

Potential Market Applications of the Technology

With ~14,000,000 patients with treatment-requiring HF in the USA, Western Europe and Japan there is a potential market size of ~ US\$15 billion annually if the cost of the single best known drug in Australia, carvedilol, is used as a bench mark. The incidence of Heart Failure is characterised as “epidemic” in the US. Heart Failure drug sales will be driven by the introduction of new, more effective drug compounds such as this new class and the ageing population.

Competitors

This will be a fourth class of drugs used in the treatment of heart failure in addition to those currently used (angiotensin converting inhibitors, aldosterone antagonists and beta blockers) and could be more effective.

Sustainable Advantage

More effective drugs are required to treat heart failure and this fourth class may prove to be it. Whereas the effects of the three presently used classes of drugs for heart failure (angiotensin converting inhibitors, aldosterone antagonists and beta-blockers) are limited to counterbalancing the effects of the heart failure-induced changes in the renin-angiotensin-aldosterone axis and in catecholamine levels, such a limitation will not apply to drugs from the fourth class. This may give this class of drugs superiority relative to the three existing classes of drugs.

Status of Intellectual Property

An International (PCT) Patent Application no. PCT/AU2005/000590 was filed by Northern Sydney and Central Coast Area Health Service on 26 April 2005. The patent covers use in the treatment of HF of the class of drugs studied. The patent is undergoing International Examination.