

New 2010 Atrial Fibrillation Guidelines Highlight Divide Between the Canadian Cardiovascular Society and Common Drug Review's Positions on Treating Atrial Fibrillation

~ Multaq™ recommended as first-line treatment in new 2010 Atrial Fibrillation Guidelines, but Canadians have limited access to treatment ~

LAVAL, QC, Oct. 27 /CNW/ - The Canadian Cardiovascular Society (CCS) presented its new *2010 Atrial Fibrillation Guidelines*, the first update in six years, at the Canadian Cardiovascular Congress (CCC) in Montreal. The guidelines, developed by an independent panel of top experts in the field of atrial fibrillation, recognize the therapeutic value of sanofi-aventis' drug, Multaq™ (dronedarone), by recommending it as a first-line treatment option for non-permanent atrial fibrillation patients with preserved heart function.¹

The CCS guidelines are in concert with those of the European Society of Cardiology (ESC), which also recently recognized Multaq as a first-line treatment in its *2010 Guidelines for the Management of Atrial Fibrillation*.² This demonstrates a significant departure from Canada's drug review program, the Common Drug Review (CDR), whose recommendation to the provinces was not to reimburse Multaq for patients suffering from atrial fibrillation. Despite the conclusions of two world renowned expert panels, CDR fails to recognize the therapeutic value of Multaq, limiting Canadian patients' access to benefit from this innovative treatment option and reducing health care practitioners' ability to implement medical best practices.

The CCS guidelines are based upon exhaustive reviews of relevant published research undertaken by health care professionals recognized across Canada and around the world for their expertise. CCS guidelines are useful for establishing patient care standards and serve as a balanced and trustworthy reference for Canadian healthcare professionals.³

"The CCS guidelines are the gold standard in Canada and bring into question CDR's scientific evaluation of Multaq's clinical value and the process behind its recommendation," said Hugh O'Neill, President and CEO of sanofi-aventis Canada. "This isn't just about Multaq - this is about all innovative drugs that have the power to change a person's life for the better and yet will not be available because of an unclear and non-transparent CDR review process."

Unlike other countries, including the United States, U.K., France, Germany, Spain and Italy, that reimburse Multaq for atrial fibrillation patients, the drug is not available on the public formularies of any province in Canada. The CDR review process, when compared to the UK's National Institute for Clinical Excellence (NICE) and Australia's Pharmaceutical Benefits Advisory Committee (PBAC), has the lowest overall probability of listing (49.6 per cent versus 87.4 per cent and 54.3 per cent, respectively).⁴ These statistics confirm the trend that the role of therapeutic innovation is being increasingly outweighed in the CDR review process by provincial drug budget pressure.

Atrial fibrillation is the most common cardiac arrhythmia (abnormal heart rhythm), affecting an estimated 250,000 Canadians.⁵ Symptoms of atrial fibrillation can have a negative impact on a patients' physical, social and mental well being that lead to significant morbidity and mortality and result in hospitalizations.⁶ It is one of the leading causes of stroke, with up to 15 per cent of all strokes being attributed to the condition.⁵ There are approximately 32,206 hospitalizations due to atrial fibrillation in Canada each year, resulting in \$203.6 million in healthcare costs.⁷ Multaq is the first and only anti-arrhythmic drug indicated to reduce the risk of cardiovascular hospitalization, which results in potential savings to the health care system.

"The significance of dronedarone is not just the efficacy it has shown in symptom control, but the ability dronedarone has shown to reduce hospitalizations and other cardiovascular events, as demonstrated in the ATHENA study," said Dr. Stuart Connolly, Director, Division of Cardiology, McMaster University in Hamilton, one of the leaders of the ATHENA clinical trial. "I hope that the recommendations presented in the CCS guidelines will encourage greater access to this important and treatment option with a good safety profile for patients with atrial fibrillation."

About sanofi-aventis

Sanofi-aventis, a leading global pharmaceutical company, discovers, develops and distributes therapeutic solutions to improve the lives of everyone.

Sanofi-aventis is represented in Canada by the pharmaceutical company sanofi-aventis Canada Inc., based in Laval, Quebec, and by the vaccines company Sanofi Pasteur Limited, based in Toronto, Ontario. Together they

employ more than 2,000 people across the country. With combined R&D investments of \$181.6 million in 2009, they are leaders in Canada's biopharmaceutical sector, a critical knowledge-based industry that generates jobs, business and opportunity throughout the country.

References

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