

## **ESC Atrial Fibrillation Guidelines Dronedarone and the PALLAS Trial Results**

The European Society of Cardiology (ESC) is aware of the early termination of the PALLAS trial (a randomised dronedarone versus placebo outcomes study in patients with permanent atrial fibrillation and cardiovascular risk) because of adverse outcomes associated with dronedarone.

Current ESC Guidelines for the Management of Atrial Fibrillation (AF) recommends the use of dronedarone in patients with atrial fibrillation as an antiarrhythmic agent to prevent recurrence of the arrhythmia, and to reduce the ventricular rate in patients with non-permanent atrial fibrillation (strictly in accordance with the indications approved by the European Medicines Agency) and to prevent cardiovascular hospital admissions (in line with the FDA approved indication, and consistent with the data included within the Summary of Product Characteristics approved by the EMA).

The European Guidelines strongly advise against administration of dronedarone to any patient with NYHA Class III or IV or recently unstable (decompensation within the last 4 weeks) heart failure.

Both the EMA and FDA have advised that the use of dronedarone should be restricted to the approved indications, and that dronedarone should not be used in patients with permanent atrial fibrillation. The ESC Guidelines are consistent with this advice.

Both agencies are presently reviewing the benefit-risk of dronedarone and will issue new regulations for dronedarone in due course. The ESC will produce a focused update of the AF Guidelines when the results of PALLAS have been published and regulatory authorities have revised the labeling for dronedarone. The focused update of the AF Guidelines will also allow the incorporation of formal recommendations relating to the use of vernakalant, one or more of the new anticoagulant agents that are alternatives to warfarin, and left atrial appendage closure devices.

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*To reduce the burden of cardiovascular disease in Europe*

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