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Cardiology in 2015: FDA Approvals and More

2015 saw the approval of numerous cardiovascular medicines and devices providing clinicians with advanced and new treatment options. *Healthmanagement.org* previously reported the top five stories in cardiology this year and now presents some more highlights in this segment:

See also: 2015 in Review: Top 5 Stories in Cardiology

FDA Approvals

The FDA approved the first two proprotein convertase subtilisin kexin type 9 (PCSK9) inhibitors alirocumab and evolucumab. The drugs were proven clinically effective in lowering LDL cholesterol. There are however concerns that the drugs were approved before it was determined that they were effective at preventing or delaying major cardiovascular events. The high price of the drugs also remained a controversial issue. The debate about the benefits of the drugs, their impact on cardiovascular outcomes and their high price is expected to continue in the years to come.

Other cardiovascular drugs and devices that were approved in 2015 include sacubitril/valsartan for heart failure and reduced ejection fraction, ivabradine for reducing risk of hospitalisation in patients with heart failure, edoxaban to reduce risk of stroke and to treat deep vein thrombosis and pulmonary embolism, perindopril argenine and amplodipine fixed dose combination for hypertension, ambrisentan and tadalfil combination to reduce risks of disease progression and hospitalisation for worsening pulmonary hypertension and patiromer for hyperkalaemia.

MERGERS AND ACQUISITIONS

The most noteworthy acquisition was that in the cardiovascular devices segment. Medtronic acquired Covidien for approximately $50 billion. The new company headquarters is now based in Ireland and will allow the companies to further expand their hold in the cardiovascular devices business including implantable therapies such as pacemakers and defibrillators, valves, catheter-based ablation systems, stents and vascular and peripheral technologies.

TAVR

Transcathether aortic valve replacement procedure continued with the number of centres performing TAVR doubling from 156 to 349 between 2012 and 2014. It is estimated that the compound annual growth rate for TAVR valves is likely to increase by 19.7 percent between 2013 and 2020. The FDA approved the Core Valve device this year for use in valve-in-valve procedures in inoperable and high-risk patients. It also approved CoreValve Evolut R, a new generation device for treating patients with severe aortic stenosis, Sapien 3 for high-risk patients with severe aortic stenosis and Sapien XT transcathether heart valve for aortic valve-in-valve procedures.

Source: Cardiovascular Business

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