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MERCK, ASTRAZENECA - Positive recommendation by FDA advisory committee for Use of Vytorin in Predialysis CKD patients: Lipitor generic entry more detrimental to Cres

https://marketpublishers.com/r/M8630E209A7EN.html
Date: November 2011
Pages: 2
Price: US$ 90.00 (Single User License)
ID: M8630E209A7EN

Abstracts

FDA endocrinologic and metabolic drugs advisory committee unanimously (14-0) recommended approval for Vytorin for reduction of CV risk in pre-dialysis chronic kidney disease patients. The committee’s vote was mixed (10-6 not in favor) for approval in ESRD (end stage renal disease) patients. The USFDA verdict on the Vytorin is expected in 1Q 2012 and if the USFDA endorses, it will rejuvenate clinicians interest in Vytorin and thus help Vytorin differentiate and retain a fair share despite Lipitor generic entry (November 30th). Out of ~24m CKD patients in US, ~15% patients have GFR

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