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ASTELLAS - FDA Accepts Mirabegron NDA - Signals Elimination of Glaucoma Concerns - Approval Should be on Time!

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Abstracts

FDA has accepted NDA of mirabegron (first in class ?3-AR agonist, overactive bladder syndrome, OAB). Glaucoma safety issues had surfaced in Nov-10 and raised concerns over the fate of this important candidate for Astellas whose aim is to maintain its leadership in urinary segment after Harnal and VESIcare. After reviewing the data in March, 2011 and meeting the management, we had expected mirabegron to come out clean and reach the market on time. We are expecting, mirabegron will be targeted 30% of patients on antimuscarinic therapy who experience anti-cholinergic SEs and should come at premium pricing.

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