

# **Astellas, Mirabegron PDUFA on 29th – Doubts Prevail Over Favorable Outcome!**

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## **Abstracts**

We are skeptical if the FDA will approve Mirabegron (first in class  $\beta$ -3-AR agonist, overactive bladder syndrome, OAB) on approaching PDUFA date on June 29th. Despite the fact that CV risk concerns raised with Mirabegron are mild in nature and the FDA's Advisory Committee recommended that the risk/benefit profile of the drug is favorable (April 5th, in 7:4 ratio) - we think that FDA will not consider the factors discussed at advisory panel in isolation.

However, in case of timely approval, which seems to be more common view of street - we expect mirabegron to generate \$300m revenue by 2016 from USA; our WW peak sales estimates from mirabegron is \$550m.

## Contents

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Astellas

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