

Safety Issues May Hit Gilenya

Two Case Reports Published

Drug Name: **Gilenya**
(fingolimod)

Developer: **Novartis (NVS)**

Indication: **Multiple Sclerosis**
(MS)

2018 Worldwide Revenue
Estimate: **\$1,666** million,
unchanged

Next Catalysts: **FREEDOMS II,**
results expected in
September.

- Two case reports published this month call attention to the evolving safety profile of Novartis' (NVS) Gilenya for multiple sclerosis (MS).
- Gallego-Pinazo and colleagues describe a case of **branch retinal vein occlusion** occurring in a 47-year-old woman who had been treated with Gilenya for six years (*J Neuroophthalmol.* 2011 Sep; 31(3):292-3).
- Conzett and colleagues present a case report of **melanoma ex naevo** occurring in a 41-year-old woman after 57 months of treatment with Gilenya (*Arch Dermatol,* Aug 2011; 147: 991-992).
- Neither of these case reports shows a causal relationship between Gilenya and the adversity.
- Still, the association of Gilenya with melanoma is not new. The TRANSFROM study showed an association with cutaneous malignancies including malignant melanoma with Gilenya. In the FREEDOMS I trial, that association was not apparent. The recently completed FREEDOMS II trial will be the tiebreaker. Data are expected by the end of September.
- Although our revenue forecast for Gilenya remains unchanged at **\$1.7 billion in 2018 worldwide revenue**, inThought continues to be cautious about Gilenya's adversity profile, noting the risk that these or other serious adversities could result in significantly less use than our model predicts.

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