
This review summarizes Phase III clinical trial data available for fingolimod. The main purpose is to evaluate the benefit-risk profile of fingolimod, the first oral compound available for treatment of multiple sclerosis (MS) and just recently approved by the European authorities. The authors place this evaluation in the context of the known safety and efficacy profile of established compounds for therapy of MS to outline the current and future potential of fingolimod. The authors conclude that only long-term safety data from post-marketing surveillance plans, together with additional head-to-head studies, would allow evidence-based treatment decisions. Furthermore, risk-profile analyses including patient history, exposure data to certain pathogens, and genetic analyses may potentially help to choose the right drug for individual patients in the future. Until these approaches toward an individualized medicine have been validated, treatment decisions for one or the other compound will have to be based partly on class IV evidence. Therefore, a close dialog with the well-informed patient, secured by effective risk mitigation plans, is required to choose the compound.