

Case of PML

12th June, 2015



The pharmaceutical sponsor of Gilenya (fingolimod), Novartis, has this week reported one case of Progressive Multifocal Leukoencephalopathy (PML) in an individual currently being treated with Gilenya in Europe.

Novartis reports that over 119 000 people around the world have been treated with Gilenya.

This current case is complicated by the individual also receiving treatment for other concurrent illnesses in addition to MS, and it is not yet clear the extent to which Gilenya has contributed to this event.

Progressive multifocal leukoencephalopathy (PML) is a rare and potentially fatal viral brain infection characterised by progressive damage to the white matter of the brain. It is caused by the JC virus (JCV), which is present in about half of the general population, but only manifests in people whose immune system has been suppressed, including those on immunosuppressive medication. PML in people with MS is known to be a relatively rare safety risk of natalizumab treatment, with most cases of PML occurring after more than two years of natalizumab treatment.

This event should not be a cause for alarm in people currently taking Gilenya, and it is very important that people should not make any changes to their current medication regimen without first seeking medical advice. If you have any concerns about your current treatment plan, please speak to your neurologist.