Withdrawn MS drug returns to market

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Just months after receiving FDA approval, natalizumab, a medication for the treatment of multiple sclerosis (MS) and other inflammatory disorders, was voluntarily withdrawn by its manufacturers after three patients developed a brain infection known as Progressive Multifocal Leukoencephalopathy (PML).

Natalizumab has recently been re-approved by the FDA, and a comprehensive article published in the latest issue of CNS Drug Reviews provides a timely overview of the drug, its pharmacological properties, clinical efficacy, safety and toxicology.

MS is a disorder that affects the central nervous system, with leukocytes (inflammatory cells) attacking the body's neurons and causing serious damage. A highly effective immunosuppressive treatment, natalizumab is an antibody that prevents leukocytes from crossing blood vessel walls into tissues such as the brain and spinal cord. The drug may also benefit secondary lymphoid organs, such as lymph nodes and the spleen, and inhibit reactivation in the central nervous system. It has been shown to significantly reduce leukocyte cell numbers in spinal fluid, with benefits continuing for six months after treatment.

"The release of natalizumab ushers in a new era in the treatment of MS," says Dr. Olaf Stüve , author of the study, noting, however, that while the short-term risk-benefit ratio appears positive, the long-term risks remain unknown. "As therapy with natalizumab resumes worldwide, the neurologic community will garner more information about the long-term risks and benefits of this powerful therapeutic medication," but for now natalizumab use is being strictly monitored. Both the FDA and TOUCH, a special distribution program designed to prevent patients not qualified for the treatment from receiving the drug, are working to make sure that any potential infectious complications are identified as early as possible.

Source: Blackwell Publishing Ltd.