Pharma major Roche launches breakthrough therapy to treat Multiple Sclerosis in India

Multiple Sclerosis is a chronic disease that affects the central nervous system. The majority of people with MS have relapsing forms of MS (RMS) or Primary Progressive MS (PPMS) at diagnosis.



Launch of Ocrevus in Delhi today.

Roche Pharma India on Tuesday announced the launch of its blockbuster breakthrough drug, Ocrevus (Ocrelizumab), for the treatment of multiple sclerosis (MS). With this launch, the pharma major expanded its neurology portfolio to cater to the unmet needs of numerous patients grappling with this debilitating disease in India.

The majority of individuals are diagnosed with multiple sclerosis between the ages of 20 and 40, making the disease a leading cause of non-traumatic disability in younger adults.

It is the only monoclonal antibody drug approved for the treatment of both Relapsing Forms of MS (RMS) or Primary Progressive MS (PPMS) with more than 10 years of clinical and Real-world data that highlights:

- Over 80% of people with RRMS and over 33% of people with PPMS treated with Ocrevus showed no signs of disability progression
- Starting Ocrevus two years earlier saved almost 10 years of disease progression in people with RRMS
- 92% of people with RRMS who received Ocrevus earlier, did not need a walking aid
- 80% of people with PPMS did not require a wheelchair after 10 years of initiating and continuous therapy with Ocrevus

According to the company, patients on OCREVUS have the highest persistence and superior adherence to treatment because of its twice yearly (once every six months) dosing which is preferable for most patients compared to more frequent (monthly) injections. Around 80 percent of patients adhered to the twice-yearly dosing of OCREVUS after their second year of treatment compared with other DMTs.

"It is the single-largest product of Roche globally across disease areas in its portfolio as compared to the oncology segment also. As it is already present in more than 100 countries...in the US it is one of the number one prescribed disease-modifying therapies compared to any other disease-modifying therapy due to its clinical efficacy as well as safety and administration convenience. Our drug, Ocrevus, is also the first and only approved Disease-Modifying Therapy (DMT) for both Relapsing-Remitting Multiple Sclerosis (RRMS) and Primary Progressive Multiple Sclerosis (PPMS). Also, these factors led to its global success and we are happy to bring it to India now," Asit Sabat, Director-Cluster Head (Indian Leadership Team), Roche told Financial Express.com during a press conference today.

He also informed that they have launched multiple products in India from their global portfolio. "This launch is also a part of our neurology segment expansion in India," he added.

On <u>market</u> expectation, he told *Financial Express.com*: "It has been so successful globally and now we expect the significant improvement in treatment access of these patients."

Ocrevus is the only MS treatment that has demonstrated a consistent and significant impact on slowing disability progression across the spectrum of MS. It is the first and only approved therapy for both PPMS & RMS with more than 300000 Patients treated globally. Ocrevus was designated as a Breakthrough Therapy by the U.S. Food and Drug Administration (FDA), and approved by the FDA in March 2017 and by the European Commission in January 2018.

The novel therapy is expected to cost around Rs. 3 Lakhs and the total treatment may cost upto Rs. 10-12 Lakhs, sources told *Financial Express.com*. According to the drug's website intended for US residents, the current list price of Ocrevus is \$75,102 annually.

During the press conference, Dr. Viraj Suvarna, Chief Medical Officer at Roche Pharma India said that the extensive clinical trial data for Ocrevus stands as the most substantial evidence for any medication in significantly slowing disability progression in primary progressive MS.

"Moreover, it reveals superior outcomes in terms of brain atrophy and disability progression for early initiators of Ocrevus compared to those who switched to the drug after receiving interferon treatment for relapsing MS (RMS). These findings strongly advocate for the adoption of Ocrevus as the first line of treatment and the established standard of care across the entire spectrum of MS," Dr. Suvarna stated.

In India, the product is approved for both relapsing and primary progressive forms of multiple sclerosis. Some experts also maintain that this therapy is distinct from existing therapies for MS.

MS is a chronic disease that affects the central nervous system. In MS, the immune system attacks the myelin sheath, causing the nerves to become exposed, due to which our nerves cannot transmit signals properly. The majority of people with MS have Relapsing Forms of MS (RMS) or Primary Progressive MS (PPMS) at diagnosis.

According to Padma Shri Dr. (Prof.) M.V Padma Srivastava, Chairperson, Neurology- Paras Hospitals, there is a critical need for medications that can effectively manage disease activity and impede disability progression.

"Despite seemingly stable clinical symptoms, individuals with all forms of MS encounter underlying disease activity, marked by inflammation in the nervous system and irreversible loss of nerve cells in the brain. The paramount objective in MS treatment is to promptly reduce disease activity, thereby slowing the pace of disability progression. For those with relapsing MS (RMS) who persist in experiencing disease activity and worsening disability despite available treatments, Ocrelizumab emerges as a breakthrough solution. I also strongly recommend early initiation of such treatment for better outcome," Dr. Srivastava said during the press conference.

Meanwhile, Multiple Sclerosis Society of India (MSSI) National Honorary Secretary Sandeep Chitnis said that detecting and diagnosing MS is often challenging due to the sporadic nature of early symptoms, the presence of similar warning signs in other central nervous system diseases, and the absence of a conclusive neurological or laboratory test for MS confirmation.

"Initiating treatment at the earliest stages with a therapy that addresses progression, and not just relapses, becomes imperative to safeguard the physical and mental capabilities of individuals with MS. This approach aims to minimize the impact of the disease on their daily lives and extend their independence for as long as possible," he said.

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