Website address:
https://www.gesundheitsindustrie-bw.de/en/article/press-release/multiple-sclerosis-new-treatment-significantly-reduces-relapses

Multiple Sklerose: Neuer Wirkstoff reduziert Krankheitsschübe deutlich

A new treatment could improve care for people with relapsing multiple sclerosis (MS). In two international studies involving a total of 2,007 patients, remibrutinib reduced the annualized relapse rate by 31% to 35% compared with an established MS therapy. New inflammatory brain lesions were also significantly less frequent. In addition, there are indications that the treatment may slow the progression of physical disability. Remibrutinib was generally well tolerated and showed no evidence of severe drug-induced liver injury. The results were published in The Lancet on October 23, 2026, and presented simultaneously at the global MS congress in Toronto.

"The results could significantly improve the treatment of people with multiple sclerosis. With remibrutinib, we have a treatment that reduces relapses and inflammation in the brain and may also slow the progression of permanent disability," says Prof. Dr. Heinz Wiendl, first and corresponding author of the publication and Medical Director of the Department of Neurology and Neurophysiology at Freiburg University Medical Center. Scientific oversight of the global study program was provided by an international Steering Committee chaired by Wiendl.

Less inflammation and a lower risk of disability

Multiple sclerosis is a chronic inflammatory disease of the central nervous system that can cause visual disturbances, muscle weakness and difficulty walking, among other symptoms. The goal of treatment is to prevent relapses and permanent disability as far as possible.

Patients receiving remibrutinib developed 65% to 70% fewer new or enlarging inflammatory brain lesions than those receiving the comparator medicine teriflunomide. During the studies, 55% of patients treated with remibrutinib showed no measurable disease activity, meaning no relapses, confirmed disability progression or new inflammatory lesions. The corresponding figure for teriflunomide was 32%.

A potential benefit was also observed in the progression of physical disability. Disability progression sustained for at least six months occurred in 7.7% of patients treated with remibrutinib, compared with 10.5% of those receiving teriflunomide. Whether this benefit is confirmed over the longer term will be evaluated in the ongoing extension phase of the studies, which includes treatment for up to five years.

Good tolerability and convenient oral administration

The favorable safety profile is particularly important. Liver injuries had occurred with other medicines in the class known as BTK inhibitors during MS studies. No corresponding serious safety signal was observed with remibrutinib. Markedly elevated liver enzyme levels were less frequent than with teriflunomide, occurring in 2.0% versus 7.4% of patients. No severe drug-induced liver injuries meeting the criteria of Hy's Law were observed.

Overall, adverse events occurred at a similar frequency with both treatments. However, fewer patients discontinued treatment because of side effects with remibrutinib than with the comparator therapy.

"Liver safety has so far been the critical hurdle for the entire class of BTK inhibitors. Alongside efficacy, the fact that we saw no evidence of severe liver injury among approximately 1,000 patients treated with remibrutinib is the most important finding," says Wiendl.

Remibrutinib selectively affects immune cells involved in inflammatory processes in MS. The treatment also enters the brain and could influence inflammation associated with disease progression. Another advantage is that remibrutinib can be taken as a tablet and does not need to be administered by infusion.

To date, remibrutinib has not been approved for the treatment of MS. The manufacturer, Novartis, plans to apply for regulatory approval based on the study results. The two manufacturer-sponsored Phase III studies, REMODEL-1 and REMODEL-2, were conducted at 407 centers across 46 countries.

Original publication:

Wiendl H, Bermel R, Airas L et al., Remibrutinib versus teriflunomide in relapsing multiple sclerosis (REMODEL-1 and REMODEL-2): two randomised, phase 3 trials
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Further information

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