

New drug expands treatment opportunities for rheumatoid arthritis

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In its final Phase III clinical trial, a new drug for treating rheumatoid arthritis has proved to be at least as effective as the current "gold standard" treatment for this autoimmune disease. This opens up new

treatment options for affected patients. The results of the international multicenter study led by MedUni Vienna were recently published in the *New England Journal of Medicine*.

Currently, a combination of the drugs adalimumab (which inhibits the mediator of inflammation TNF (tumor necrosis factor) and [methotrexate](#) (a folic acid antagonist) is one of the most effective options ("gold standard") for patients who fail to respond adequately to [initial treatment](#) with methotrexate. Despite this and other effective [drug](#) regimens, up to 25% of patients do not respond well to any of the currently available therapeutic options.

The new drug olokizumab is a humanized monoclonal antibody that directly targets the interleukin-6 cytokine. This is a messenger molecule that, like TNF, activates [inflammatory responses](#) in the body and is involved in the progression of joint damage in [rheumatoid arthritis](#). Olokizumab is the first direct inhibitor (blocker) of interleukin-6 which will soon be filed for approval for commercial use for this indication.

In this Phase III clinical trial with more than 1,600 volunteers, the efficacy of the new drug in combination with methotrexate was tested against placebo and adalimumab plus methotrexate. This new therapy proved to be more efficacious than placebo and at least as effective as the current gold standard.

"The new drug helps many patients with rheumatoid arthritis who failed methotrexate to achieve so-called low disease activity, which is the primary therapeutic goal in this population. Complete disappearance of symptoms of active disease, so called remission, occurs in 1 out of 8 patients," explains study lead Josef Smolen from the Division of Rheumatology within the Department of Medicine III at MedUni Vienna and University Hospital Vienna. "This [new therapy](#) will significantly expand the range of treatment options, since this agent has a different

mode of action than all other drugs."

"This will give us another excellent treatment opportunity for our patients," explains Daniel Aletaha, Head of the Division of Rheumatology. "We soon will have another option for those patients who do not respond to a first or subsequent therapies."

The new drug is about to be filed for approval in the EU and the U.S. within the coming year. The researchers expect it to be in clinical use soon thereafter.

Rheumatoid arthritis is a chronic autoimmune disease that primarily affects women (approximately two thirds of those affected) and is usually diagnosed between the ages of 40 and 70. Approximately 1% of the world's population suffers from rheumatoid [arthritis](#). The disease causes inflammation of the joints, resulting in swelling, overheating and functional impairments. If left untreated, it leads to gradual destruction of the joints and the neighboring bone, causing misalignment, malformation, and permanent and progressive disability. About 80,000 people in Austria suffer from this disease.

More information: Josef S. Smolen et al, Olokizumab versus Placebo or Adalimumab in Rheumatoid Arthritis, *New England Journal of Medicine* (2022). [DOI: 10.1056/NEJMoa2201302](https://doi.org/10.1056/NEJMoa2201302)

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