

Marinomed Biotech AG publishes remarkable results showing alleviation of allergic eye inflammation in patients treated with Tacrolimus eye drops in peer-reviewed journal

- Tacrosolv eye drops, a low-dose, aqueous Marinosolv-enabled formulation of Tacrolimus, are safe and effective in alleviating symptoms of allergic rhinoconjunctivitis
- Data from phase II dose-finding clinical trial have been published in peer-reviewed Clinical Ophthalmology journal
- Tacrosolv offers great potential in treatment of inflammatory diseases of the ocular surface

Korneuburg, Austria, 08. October 2024 – Marinomed Biotech AG (VSE:MARI) has published clinical data from the phase II dose-finding clinical trial evaluating the efficacy of Tacrosolv eye drops in patients with allergic rhinoconjunctivitis in the peer-reviewed [“Clinical Ophthalmology”](#) journal. The placebo-controlled allergen challenge trial assessed the efficacy and safety of two different doses of Tacrosolv. The results show that the higher dose of Tacrosolv eye drops (0.005% Tacrolimus) significantly reduced ocular symptoms of allergic conjunctivitis, and surprisingly, also the associated nasal allergy symptoms. Remarkably, these results were achieved with a dose that is 20-fold lower than that of the only Tacrolimus eye drop product currently on the market.

Eva Prieschl-Grassauer, CSO of Marinomed, comments: “Tacrolimus is an immunosuppressive compound widely used to prevent organ rejection after transplantation or for treating inflammatory skin and eye diseases. In ophthalmology, there is currently only one marketed product in Asia in which Tacrolimus is used as a suspension. Due to its very low solubility in water and the associated very low bioavailability in the inflamed tissue, it takes days to weeks for the therapy to take effect. With our Marinosolv solubilization technology, we could significantly increase the solubility of Tacrolimus in a water-based formulation, thereby improving bioavailability, lowering the needed dose, and leading to a faster onset of action. The encouraging results of this clinical study show that Tacrosolv is a safe and effective treatment option for ocular inflammation. Tacrosolv has

the potential to benefit a multitude of inflammatory eye diseases, where the currently limited treatment options create unmet medical need.”

In the clinical trial, adults with a history of allergic conjunctivitis were randomized to either Tacrolimus or placebo treatment for 8 days. Allergic symptoms were induced by controlled allergen exposure on day 1 and 8. During exposure, participants recorded ocular, nasal and respiratory allergy symptoms. The primary endpoint was the mean Total Ocular Symptom Score (TOSS) on day 8. Objective ocular safety parameters were assessed before, during and after exposure.

On day 8, ocular symptoms (mainly redness and watery eyes) were reduced in participants receiving Tacrosolv compared to placebo treatment. Surprisingly, nasal symptoms (mainly itching and sneezing) were significantly reduced in participants treated with Tacrosolv already after the first application. This is an outstanding finding, as the only currently marketed eye drop formulation (Talymus® ophthalmic suspension 0.1%, marketed in Asia) contains a 20-fold higher concentration of Tacrolimus. In conclusion, treatment with Tacrosolv at the dose and frequency studied is safe and significantly alleviates symptoms in participants suffering from allergic rhinoconjunctivitis.

About Marinosolv®:

Marinosolv® is an innovative technology platform that enables the solubilization and enhances the bioavailability of small molecules and peptides that are hardly soluble in aqueous formulations. Consequently, new treatments of a multitude of diseases can be envisaged. The use of the Marinosolv® technology can facilitate efficient drug delivery with a low systemic off-target activity. Existing drugs and off-patent active ingredients can be improved and re-patented as part of new formulations using Marinosolv®. Under the brand Solv4U, Marinomed provides Marinosolv® formulation development in technology partnerships for active ingredients at all stages of drug discovery and for lifecycle extension. For more information on Marinosolv® or Solv4U, please visit <https://www.solv4u.com>. Scientific publications on Marinosolv® can be accessed in the “Immunology” tabs at <https://www.marinomed.com/en/news/scientific-publications>.

About Marinomed Biotech AG

Marinomed Biotech AG is an Austrian, science-based biotech company with a growing development pipeline and globally marketed therapeutics. The Company develops innovative patent-protected products in the therapeutic areas immunology and virology based on the platform Marinosolv® and the virus-blocking activity of Carragelose®. The Marinosolv® technology improves the solubility and bioavailability of hardly soluble compounds and is used to develop new therapeutics for autoreactive immune disorders. The virology segment includes Carragelose®-based over-the-counter (OTC) products to prevent and treat respiratory viral infections that are partnered in more than 40 countries. The Company is headquartered in Korneuburg, Austria, and is listed on the Vienna Stock Exchange (VSE:MARI). For further information, please visit: <https://www.marinomed.com>.

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