Marinomed Biotech AG Reports Encouraging Topline Data for Phase II Clinical Trial of Tacrosolv in Allergic Rhinoconjunctivitis

- Phase II trial with Tacrosolv eye drops against allergic rhinoconjunctivitis (hay fever in eyes and nose) shows dose-related efficacy
- Tacrosolv, a novel aqueous formulation of solubilized tacrolimus, is the first ocular application of a Marinosolv-based investigational medicinal product
- First time application of low concentrated tacrolimus resulted in significant reduction of ocular and nasal allergic symptoms

Korneuburg, Austria, 01 July 2021 – Marinomed Biotech AG (VSE:MARI), an Austrian science-based biotech company with globally marketed therapeutics derived from innovative proprietary technology platforms, announced today the topline results for its Phase II clinical trial of Tacrosolv eye drops to treat ocular hay fever symptoms. The placebo-controlled Phase II clinical trial was conducted at the Vienna Challenge Chamber (Austria) to assess safety and efficacy of two different dose of Tacrosolv in a crossover design. The applied doses contained only 2.5 % and 5 % of the dose used in Tacrolimus eye drops that are marketed in Japan for the treatment of vernal conjunctivitis. After one week of treatment, the higher dose resulted in a statistically significant reduction of ocular symptoms in the time period starting 3.5 hours after the challenge ($p < 0.05$). A comparison of the ocular symptoms on day 1 with day 8 showed a significant reduction of symptoms in the case of Tacrosolv treatment ($p < 0.01$) without any effect of the placebo treatment. Additionally, nasal symptoms were assessed and showed a significant reduction at day 8 (between 0 to 4 hours after the challenge, $p < 0.05$). These results indicate the high potential of tacrolimus being an effective treatment of ocular inflammation exemplified by allergic conjunctivitis and other allergic manifestations.

“The higher dose showed significant relief of allergic symptoms in the eyes and also in the nose. The latter is surprising and supports the effectiveness of Tacrolimus also in allergic rhinitis. This topline data strongly supports our hypothesis that a fully solubilized Tacrolimus can be developed as an effective therapy for ocular inflammation including dry eye disease and rhinoconjunctivitis,” commented Dr. Eva Prieschl-Grassauer, Chief Scientific Officer of Marinomed.

The study was conducted as a randomized, placebo-controlled, crossover, double-blind, single site Phase II clinical trial. Patients received Tacrosolv eye drops (50 µg / ml eye drop) in either a high (two drops per day) or low dose (one drop per day) compared to placebo (3 % propylene glycol in saline) in two treatment cycles. In the first treatment cycle, patients were administered Tacrosolv or placebo for 8 days. This was followed by a washout period of at least 13 days. In the second treatment cycle, treatment was switched to placebo or Tacrosolv eye drops, respectively.

Tacrolimus is a macrolide immunosuppressant used for various inflammatory conditions. Currently, the only available tacrolimus-containing eye drop product is formulated as a suspension at 1 mg / ml and marketed in Japan. Tacrosolv is a novel aqueous formulation of solubilized tacrolimus based on the Marinosolv platform developed by Marinomed. By complete solubilization of the active ingredient, the new formulation allows the use of low

concentrated tacrolimus resulting in a scientifically proven enhanced bioavailability to reduce ocular inflammation.

About Marinosolv®:
Marinosolv® is an innovative technology platform that enables solubilization of many barely soluble compounds and in consequence, opens new possibilities in treating a multitude of diseases. While organic compounds could previously often only be delivered as a suspension, Marinosolv® provides aqueous formulations without preservatives with a faster onset of action and increased local bioavailability. In addition, they can be used without prior shaking, thus improving usability and enabling reliable dosing in sensitive tissues such as eyes or nose. Overall, the use of the Marinosolv® technology can facilitate efficient drug delivery with high local availability and low systemic off-target activity. Even off-patent active ingredients can be patented as part of new formulations developed using Marinosolv®, while keeping production processes cost-efficient. For more information on Marinosolv®, please visit https://www.marinosolv.com/en, and for a list of scientific publications on Marinosolv®, https://www.marinosolv.com/en/publications.

About Marinomed Biotech AG
Marinomed Biotech AG (Korneuburg, Austria) (VSE:MARI) is an Austrian science-based biotech company with globally marketed therapeutics listed on the Prime Market of the Vienna Stock Exchange. The company focuses on the development of innovative products based on two patent-protected technology platforms. The Marinosolv® technology platform increases the efficacy of hardly soluble compounds for the treatment of sensitive tissues such as eyes, nose, lung or gastrointestinal tract. The Carragelose® platform comprises innovative patent-protected products targeting viral infections of the respiratory tract and can reduce the risk of an infection with SARS-CoV-2. Carragelose® is used in nasal sprays, throat sprays and lozenges, which are sold via international partners in over 40 countries worldwide. Marinomed, Marinosolv® and Carragelose® are registered trademarks of Marinomed AG. These trademarks may be owned or licensed in select locations only. Further information is available at https://www.marinomed.com/en/technologies-markets/markets.

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