**Marinomed Biotech AG Enrolls First Patients in Phase II Clinical Trial of Tacrosolv to Treat Allergic Rhinoconjunctivitis (Hay Fever)**

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Corporate News

Marinomed Biotech AG (VSE:MARI), a globally operating biopharmaceutical company, announces that the first patients have been treated in a Phase II clinical trial evaluating Tacrosolv eye drops in allergic rhinoconjunctivitis, i.e. hay fever affecting both the eyes and nose. The clinical trial is running at the Vienna Challenge Chamber (Austria) to assess safety and efficacy of two different dosages of Tacrosolv.

Tacrosolv is an improved formulation of tacrolimus, an immunomodulator that can suppress inflammatory reactions, including allergic symptoms. Tacrolimus was first approved for human use by the U.S. Food and Drug Administration (FDA) in 1994 for use as an immunosuppressant in neurodermitis and graft-versus-host disease. The now off-patent blockbuster drug is poorly soluble in water limiting its usefulness for ophthalmic applications. Formulated with Marinomed's Marinosolv platform, the solubility of tacrolimus is increased by more than 200-fold compared to water alone enabling the use of tacrolimus as eye drops and enhancing its bioavailability, which allows for significantly lower dosing. Marinomed plans to develop its patent-protected tacrolimus formulation for the treatment of various types of ocular inflammation starting with allergic rhinoconjunctivitis.

The ongoing randomized, placebo controlled, crossover, double-blind, single site Phase II clinical trial is testing Tacrosolv in adult subjects who are suffering from grass pollen induced allergic rhinoconjunctivitis. Patients will administer either Tacrosolv eye drops (high or low dose) or placebo daily for 8 days (first treatment cycle) and after a minimum 13-day washout period, switch to either placebo or Tacrosolv eye drops (high or low dose) for another 8 days of treatment (second treatment cycle). This crossover design ensures that each patient receives either a high or low dose of Tacrosolv compared to placebo. Patients undergo a 4-hour allergen exposure challenge in a challenge chamber on day 1 (4 hours after start of treatment), and day 8 of each treatment cycle. During exposure sessions, allergy symptoms are evaluated.

The primary objective is to assess safety and efficacy of the two dosages of Tacrosolv on day 8 of treatment. Efficacy will be determined by the assessment of ocular symptoms every 15 minutes during the grass pollen challenge using the mean 'Total Ocular Symptom Score' (TOSS). This score is calculated from the sum of four ocular symptoms (ocular redness, ocular itching, watery eye, gritty feeling), each scored on a 4-point scale from 0-3 (none, mild, moderate, severe). The secondary objective is to evaluate the onset of action of the two Tacrosolv dosages on day 1 of treatment as well as differences in efficacy between high and low dose on day 8. Secondary efficacy endpoints include changes in ocular redness, the total nasal symptom score (consisting of scores for nasal congestion, rhinorrhea, itchy nose, and

sneezing), the total respiratory symptom score (sum of the scores for cough, wheeze, and dyspnea) and nasal airflow.

Dr. Petra Zieglmayer, specialist in allergology and scientific head of the Vienna Challenge Chamber and principal investigator of the study, said: “While allergic rhinoconjunctivitis may seem like a trivial condition, it can significantly impact people’s quality of life. New treatment options that are both well tolerated and user-friendly could give patients better tools to manage their disease. Tacrosolv eye drops are a promising new candidate for the treatment of ocular symptoms. Our Allergen Challenge Chamber, one of only nine worldwide, provides a cutting-edge opportunity to test Tacrosolv’s ability to suppress allergic reactions under highly controlled conditions that closely mimic the pollen exposure encountered outside.”

“With Tacrosolv, we hope to pave the way for the use of the highly potent immunosuppressant tacrolimus in various types of ocular inflammation, an effort that has so far been hampered by the insolubility of the compound. Previously, we have shown that our formulation delivers high tacrolimus concentrations to the eye while keeping systemic side effects negligible. We seek to confirm in the ongoing trial that the enhanced bioavailability of Tacrosolv offers an effective therapy, and hay fever-induced rhinoconjunctivitis is an ideal indication to demonstrate exactly that,” added Dr. Eva Prieschl-Grassauer, Chief Scientific Officer of Marinomed. “After successfully completing the pivotal Phase III trial necessary for approval with Budesolv, a steroid nasal spray against allergic rhinitis based on our Marinosolv technology, we are excited to advance the clinical development of our second Marinosolv-based product candidate, which will be for ophthalmic use.”

Allergic rhinitis and allergic rhinoconjunctivitis (hay fever) are extremely common conditions, affecting up to 25 % of people in Europe.[1] While not life-threatening, hay fever severely impacts patients’ quality of life.[2],[3] According to experts, Europe could save up to €84 billion per year with adequate treatment of allergies.[4] In the future, the ophthalmic use of Tacrosolv may be expanded to further indications beyond allergic symptoms such as dry eye disease and other types of 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) is a biopharmaceutical company 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.

[1] https://www.ecarf.org/info-portal/erkrankungen/allergischer-schnupfen/
[2] Blaiss MS Ann Allergy Asthma Immunol. 1999; 83(5):449-54. https://doi.org/10.1016/S1081-1206(10)62850-5
[3] Thompson AK et al., Ann Allergy Asthma Immunol. 2000; 85(5):338-47. https://doi.org/10.1016/S1081-1206(10)62543-4
[4] Zuberbier T et al. Allergy 2014;69(10):1275-9. https://doi.org/10.1111/all.12470

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