

Screening of pivotal clinical trial completed

December 21, 2018 Corporate News

Marinomed Biotech AG and the Vienna Challenge Chamber are happy to report the successful screening and completed inclusion of the study participants in their pivotal study BDS_18_01 with Marinomed's novel allergy treatment "Budesolv". Budesolv is a formulation of dissolved budesonide based on the proprietary Marinosolv technology that is tested in the indication of allergic rhinitis. The Marinosolv technology platform allows the solubilization of a broad range of nearly insoluble potent drug molecules. Marinomed has demonstrated significantly increased local bioavailability in the target tissues, which allows the treatment of patients with a reduced total dose of the drug.

The pivotal clinical study, which will support the market authorization application and is listed on clinicaltrials.gov, will test for therapeutic equivalence to a marketed comparator with the same drug and indication (Rhinocort™ Aqua 64). Furthermore the study is designed to test for faster onset of the therapeutic effect, which would lead to the clinical benefit of immediate relief from allergy symptoms, whereas the comparator products require pretreatment for up to 14 days to experience the full benefit of the treatment.