**Marinomed Biotech AG: Detailed clinical data show rapid onset of action of Budesolv to alleviate hay fever**

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Corporate News

Marinomed Biotech AG (Marinomed) has presented detailed data from its pivotal Phase III clinical trial for the therapeutic comparability of an aqueous solution of budesonide, a synthetic steroid for the treatment of hay fever. A nasal spray, referred to as Budesolv, is the current lead product of the company's Marinosolv® technology platform, which enables complete solubilization of difficult-to-dissolve substances, such as steroids. For the first time detailed evaluations of the data on the treatment of 75 patients were shown at the annual meeting of the American College of Allergy, Asthma & Immunology (ACAAI) in Houston, Texas. Allergy patients received Budesolv, Rhinocort Aqua (a licensed, suspension-based comparator) or placebo once daily for 8 days. Patients were exposed to grass pollen under controlled conditions for six hours on the first and last day of treatment. Budesolv contains 10 µg / spray which is approximately 85% less amount of active ingredient than the comparator product (64 µg / spray).

As a summary, the data show that Budesolv is the first steroid nasal spray resulting in a clinically relevant reduction of symptoms – with approximately 50% of the maximum efficacy, within few hours after the first single treatment.

After one week of treatment low dose Budesolv was equally active compared with the originator product Rhinocort Aqua, which requires several days pre-treatment to be effective. Dr. Eva Prieschl-Grassauer, Chief Scientific Officer of Marinomed: "This study shows that thanks to our Marinosolv® technology, an aqueous solution of an active substance can be superior to a suspension. In addition, a significantly lower amount of active ingredient is required. This is excellent data, also with regard to our further projects based on the Marinosolv® technology, such as, for example, our product Tacrosolv, a treatment for allergic conjunctivitis and dry eye."

Onset of Action

Steroid nasal sprays are currently applied as suspension with minute concentrations of the active pharmaceutical ingredient being dissolved and available. Therefore efficacy is usually reached after several applications, which can last up to one week. In contrast, Budesolv is applied as solution and therefore a fast onset of action was hypothesized. To assess its effectiveness, subjects were exposed to grass pollen under controlled conditions. Their allergic nasal symptoms as well as the allergic symptoms of the upper respiratory tract were regularly evaluated (total nasal symptom score; TNSS, respiratory symptom score, TRSS, respectively).

The first dose of Budesolv resulted in a significant reduction of the TNSS already 2.45 h after the application compared to placebo. After 4h the reduction was more than 1.2 points, which is regarded as clinically meaningful resembling approximately 50% of the maximum possible reduction. An even more pronounced result could be obtained with respect to the TRSS, where subjects rated Budesolv significantly better than placebo even within 2 hours. The comparator product Rhinocort Aqua showed no therapeutic effect for both parameters even after 4 h - with a more than 6 times higher concentration of budesonide. Surprisingly, a comparison of this product with Budesolv again showed the superiority of the new formulation which performed significantly better with respect to TNSS and TRSS.

Efficiency

To determine the comparability of the two medications, subjects were treated for a period of 8 days. The comparator product requires this time period in order to be able to show near to maximum efficiency. At the end of the period, subjects were again exposed to pollen for 6 hours and the level of their allergic reactions was recorded. Budesolv appeared to be as effective in alleviating allergic nasal symptoms as the reference product.

All in all, the anticipated primary and secondary endpoints of the study were met. Budesonide has shown to provide significant and clinically relevant benefits to hay fever patients with complete solubilization of the drug, and thus its better availability. The basis for Marinomed's planned entry into the multibillion-dollar market for allergic hay fever therapies was successfully established. The relevant world market for Budesolv currently has a volume of around USD 5 billion and is growing at an annual rate of around 5%. Marinomed is adhering to the timetable for approval of Budesolv and its subsequent launch in Europe in 2021.

Reference link to detailed data: https://epostersonline.com/acaai2019/node/2212

About Marinomed Biotech AG

Marinomed Biotech AG is a biopharmaceutical company with headquarters in Vienna and has been listed in the Prime Market of the Vienna Stock Exchange since February 1st, 2019. The company focuses on the development of innovative products based on patent-protected technology platforms in the field of respiratory and ophthalmological diseases. The Marinosolv® technology platform increases the efficacy of hardly soluble compounds for the treatment of sensitive tissues such as the eyes and nose. The Carragelose® platform comprises innovative patent-protected products targeting viral infections of the respiratory tract. Carragelose® is used in nasal sprays, throat sprays and lozenges, which are sold via international partners in over 30 countries worldwide. Further information is available at: www.marinomed.com.

For further enquiries contact:

Dr. Eva Prieschl-Grassauer
Chief Scientific Officer, Marinomed
Veterinärplatz 1, 1210 Wien, Österreich
T +43 (0)1 250 77 4460

E-Mail: eva.prieschl@marinomed.com
http://www.marinomed.com

Roland Mayrl
Managing Partner, Metrum Communications
Prinz-Eugen-Straße 80/16, 1040 Wien, Österreich
T +43 (0) 1 504 69 87 331
E-Mail: r.mayrl@metrum.at
http://www.metrum.at