PRESS RELEASE

Marinomed Biotech AG: Budesolv with a strongly decreased dose of the active ingredient compared to the marketed product Rhinocort Aqua shows pronounced efficacy already after first application – clinical validation of the Marinosolv® platform

- **Phase III study successfully completed preparing the ground for entering a multi-billion-dollar market**
- **Even after the first application, Budesolv exhibits noticable efficacy**
- **Allergic nasal symptoms markedly reduced within four hours**
- **Six times less active compound than the marketed reference product**

Vienna, May 15, 2019. The pivotal phase III study for Budesolv has provided Marinomed Biotech AG, a globally active biopharmaceutical company with headquarters in Vienna, with clinical validation of the efficacy of its innovative Marinosolv® technology platform. The available data proves that after one week of treatment, Budesolv 10µg achieves at least the same effect with a dose six times lower than Rhinocort Aqua 64µg, the current marketed reference product. Moreover, the results of the study show that the symptoms of allergic rhinitis (hay fever) improve even after the first dose of Budesolv. This effect was not observed with Rhinocort Aqua. The planned primary and secondary endpoints of the study have thus been achieved, facilitating the planned entry into the multi-billion dollar market for therapies to treat hay fever. The relevant global market for Budesolv currently has a volume of around 5 billion US dollars and is growing by around 5% annually. Marinomed is adhering to its timelines for approval of Budesolv and subsequent European market launch in 2021.

Full dissolution of the compound budesonide

Budesolv is a new formulation of the compound budesonide based on Marinosolv®. Whereas steroid nasal sprays currently marketed contain the active compounds as largely undissolved suspensions, Marinosolv® enables the substance to be fully dissolved. Budesolv contains a significantly lower concentration of the active ingredient than the comparable marketed product (actually more than six times lower with 10µg per puff compared to 64µg). A study with subjects suffering from hay fever showed that after one week of treatment, Budesolv had an equivalent effect compared to that of the marketed product despite the lower dose.

This data shows that the complete dissolution and the resulting improved bioavailability of a substance offers significant, clinically relevant benefits. The study additionally showed that allergic symptoms improve even after the first dose of Budesolv.

First innovation for years in the treatment of allergies with budesonide

Principal investigator and allergologist Dr. Petra Zieglmayer was positively surprised by the results, particularly about those from the hours following the first dose: “While it is already a major success that a product with a greatly reduced dose of the active compound compared to the marketed product achieves an equivalent effect after one week of treatment, the data following the initial dose are quite astounding. Experience with Rhinocort Aqua suggests no effect of the treatment within the first few hours after the initial dose compared to placebo. In contrast, Budesolv showed a pronounced reduction of allergic nasal symptoms within four hours compared to the symptoms before the initial dose and to placebo. This efficacy is also apparent for allergic symptoms associated with asthma. In the asthma score, a strong reduction compared to placebo immediately after the initial dose of Budesolv was confirmed. No such effect was observed with the reference product Rhinocort Aqua. Patients can therefore expect a noticeable and durable improvement in symptoms already within the first few hours after initial application of Budesolv. Budesolv thus represents the first real innovation in the treatment of allergies with budesonide in many years.”

Dr. Eva Prieschl-Grassauer, Chief Scientific Officer of Marinomed, adds: “We are delighted about the successful outcome of the first study involving a product based on the Marinosolv® technology. Our general assumptions that solutions are superior to suspensions have been confirmed. This also means that we can be optimistic about continuing our follow-on projects based on the Marinosolv® technology.” Marinomed is currently developing a therapy to treat allergic conjunctivitis using the product Tacrosolv.

Through its two flagship products Budesolv and Tacrosolv, Marinomed plans to enter the multi-billion-dollar market for the treatment of allergies and ophthalmic conditions. Marinosolv® products will be marketed through partners once approval is granted.

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 1, 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.

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