New version – corrected 17 September, 2020

Enzymatica distributed the press release about the result from its placebo-controlled, randomized study in Germany on August 17th. In this version the company referred incorrectly in the quote by Claus Egstrand that the results from the study confirmed that ColdZyme fulfilled the Cochrane criteria for evidence-based documentation. In the corrected version as of today the company has removed the reference to Cochrane and modified the quote according to what is stated below. Besides this nothing in the press release has changed, which means that the results from the study are still as valid.

The results of Enzymatica's placebo-controlled, randomized study show statistically significant shorter common colds and good treatment efficacy when using ColdZyme

The final results of Enzymatica's double-blind, randomized, placebo-controlled study in Germany provide additional clinical evidence for the use of ColdZyme® in the common cold. The results show a statistically significant favourable efficacy for the participants treated with ColdZyme compared to the placebo group. Several study parameters also show statistically significant differences or trends in favour of ColdZyme, mainly regarding shorter common colds compared to placebo. In addition, the study results confirmed the excellent safety data for the product from previous studies, but now in a larger population.

In the study conducted at 10 study centers in Germany in the spring of 2019, 701 women and men participated, out of which 438 developed symptoms of common cold and were treated randomly and double-blind with either ColdZyme or placebo, starting at their early symptoms of common cold. The assessment using with the Wisconsin Upper Respiratory Symptom Survey (WURSS-21) Quality of Life (QoL) domain and Jackson score show a slightly faster recovery with ColdZyme, i. e. symptoms and complaints affecting the quality of life were shortened by about half a day. The shorter time with a common cold confirmed previous study results.[1-3] However, the actual difference was less pronounced in the current study.

At the end of the study the participants and investigators assessed the treatment effect, unaware of the assigned treatment group. Of the participants, a larger proportion in the ColdZyme group (70.6%) rated the effectiveness of their treatment as "very good" or "good", as opposed to 60.1% in the placebo group, a statistically significant difference ($p < 0.05$) in favour of ColdZyme. The investigators also assessed the efficacy to be superior for participants treated with ColdZyme. Furthermore, the excellent safety and tolerability of the medical device shown in previous trials have now been confirmed in a larger study population.

"The results from the now completed placebo-controlled study confirm previous results that ColdZyme has the level of clinical evidence needed to demonstrate shortening of common colds between 0.5 and 3.5 days in accordance with the guideline MDCG 2020-06, published in April 2020 by the Medical Device Coordination Group. The results are also valuable for the long-term compliance with regards to the Medical Device Regulation. The fact that the users themselves experience a good effect when using ColdZyme is of course also of great value," says Claus Egstrand, Chief Operating Officer at Enzymatica.

This double-blind placebo-controlled study is a follow-up of a single-blind, prospective and controlled multicentre study with ColdZyme that was conducted at six centers in Germany in 2018. That study included 400 participants who were randomly assigned to treatment with ColdZyme at the first signs of a common cold, or to no specific treatment. A total of 267 participants with confirmed common cold were evaluated and the results showed statistically significant benefits of ColdZyme, such as reduction of the duration, alleviation of symptoms, improved quality of life and a reduction of the need for concurrent use of symptom-relieving medication during a common cold.

Title: Double-blind, Randomized, Parallel-group, Placebo-controlled Study to Evaluate Efficacy of CMS008618 for Common Cold

For additional information: https://clinicaltrials.gov/ct2/show/NCT03794804
ClinicalTrials.gov Identifier: NCT03794804

References:

[1] Clarsund, M.,Fornbacke, M., Uller, L., Johnston, S.L. and Emanuelsson, C.A. (2017) *A Randomized, Double-Blind, Placebo-Controlled Pilot Clinical Study on ColdZyme® Mouth Spray against Rhinovirus-Induced Common Cold*. Open Journal of Respiratory Diseases, 7, 125-135. https://doi.org/10.4236/ojrd.2017.74013

[2] *Multi-symptom Relief and Improvement of Quality of Life - A Comparative Multicenter Trial on ColdZyme® Mouth Spray in Common Cold*, Icelandic Medical Association conference, Jan 2019

[3] Glen Davison, Eleanor Perkins, Arwel W. Jones, Gabriella M. Swart, Alex R. Jenkins, Hayley Robinson & Kimberly Dargan (2020): *ColdZyme® Mouth Spray reduces duration of upper respiratory tract infection symptoms in endurance athletes under free living conditions.*, European Journal of Sport Science. DOI: 10.1080/17461391.2020.1771429

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ABOUT ENZYMATICA AB

Enzymatica AB is a Swedish life science company that develops and sells health care products for primarily conditions of the ear-nose-and-throat region. The products are based on a barrier technology that includes marine enzymes. The company's first product is the medical device ColdZyme®, a mouth spray against common cold. The product has been launched in about ten markets. The strategy is to continue to grow by developing more health care products and strengthening the company's position in existing markets and expanding into new geographic markets through established partners. The company has its headquarters in Lund and is listed on Nasdaq First North Growth Market. For more information, visit: www.enzymatica.com and www.enzymatica.se/en/section/media/press-releases

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