

# The evidence base for ColdZyme remains unchanged – PLOS ONE notice concerns the presentation of the Berlin II article, not the evidence base for ColdZyme

**Enzymatica AB (publ) notes that the scientific journal PLOS ONE has published an Expression of Concern regarding an article on the company's placebo-controlled Berlin II study from 2023. The notice is not a retraction. The article remains published.**

**The scientific evidence base for ColdZyme – including the independent Davison study from 2025 – remains unchanged. The same applies to the company's regulatory position.**

## **What the notice concerns**

PLOS ONE's notice concerns how certain exploratory analyses and wording were presented in the 2023 Berlin II article, rather than the conduct of the study or the validity of the underlying data.

The primary endpoint in Berlin II was not met – as clearly stated in the published article. Nevertheless, the study included 438 randomized participants, of whom 220 were in the ColdZyme group, and contributes important safety and tolerability data in a large population.

## **Davison 2025 – an independent part of the clinical evidence base**

Davison et al. (2025), conducted at the University of Kent, is an independent, randomized and peer-reviewed clinical study that demonstrated statistically significant effects across several key endpoints related to upper respiratory tract infections. The Davison study is not affected by PLOS ONE's questions regarding the Berlin II article.

## **Sana Alajmovic, CEO Enzymatica:**

"This is not new data, and it is not a retraction of the article. PLOS ONE's notice concerns how certain exploratory analyses were reported and interpreted in a specific article from 2023. It does not change the scientific evidence base for ColdZyme. The independent Davison study from 2025, which showed statistically significant results, is not affected by the notice and remains an important part of the current evidence base for ColdZyme."

## **The company's marketing and regulatory position**

Enzymatica's marketing claims for ColdZyme are based on a broader scientific foundation than the Berlin II article from 2023, including preclinical research, mechanistic data and several clinical studies, including Davison 2025.

At present, PLOS ONE's notice does not prompt any changes to the company's marketing, clinical evaluation report (CER), Summary of Safety and Clinical Performance (SSCP), or regulatory status.

**For more information, please contact:**

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**Facts: What is an Expression of Concern?**

An Expression of Concern is an editorial tool used by scientific journals to signal that a question has arisen regarding an article, without retracting the article. The article remains published and citable.

**About ColdZyme®**

ColdZyme is a clinically documented medical device mouth spray for colds and cold-like symptoms and is certified under the EU regulatory framework for medical devices, MDR Class III. The product was recently named best in test among cold sprays by the independent Swedish consumer guide [Bäst-i-Test.se](http://Bäst-i-Test.se). Read more at [www.coldzyme.com](http://www.coldzyme.com)

**About Enzymatica**

Enzymatica AB is a Swedish life science company developing scientifically backed solutions for the treatment and relief of infections and related symptoms, based on a unique barrier technology platform. Enzymatica is headquartered in Lund, Sweden, and is listed on Nasdaq First North Growth Market. Certified Adviser is DNB Carnegie Investment Bank AB (publ). For more information, please visit [www.enzymatica.com](http://www.enzymatica.com)

**Image Attachments**

[Sana Alajmovic](#)