

**CEBINA reports broad anti-viral potency of azelastine, an antihistamine widely available as a nasal spray, has potential for use against influenza and RSV infections in addition to SARS-CoV-2 and its variants of concern including the Omicron variant**

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CEBINA GmbH, Central European Biotech Incubator and Accelerator, today informs about the potential of the antihistamine drug azelastine hydrochloride to be an effective anti-viral approach against major respiratory viruses, such as SARS-CoV-2 and its variants, influenza and Respiratory Syncytial Virus (RSV). The clinical usefulness of an azelastine-containing nasal spray against SARS-CoV-2 has been previously demonstrated in a Phase 2 efficacy indicator study initiated by URSAPHARM Arzneimittel GmbH and CEBINA where a meaningful reduction in nasal viral load in COVID positive subjects was seen. Based on the broader anti-viral effect of azelastine, it is anticipated azelastine may also be effective against the recently discovered Omicron variant of concern, and experiments are underway to confirm this.

The continuous spread of the SARS-CoV-2 virus worldwide has led to a series of emerging new variants of concern, some of which have been reported to be more contagious and to have the potential to cause more severe disease than the original virus. The recently designated variant of concern B.1.1.529, Omicron, has many more mutations in the viral Spike protein than previous variants, and according to preliminary data seems to be highly transmissible and more capable of evading the immune response induced by current vaccines and prior infections. Another concerning trend is the higher incidence of certain respiratory infections that are observed after lockdown periods, especially in the winter seasons as already seen for RSV and expected for influenza. Moreover, respiratory infections can act synergistically leading to increased disease severity. Therefore, broader spectrum anti-viral agents that can prevent or interfere with the most common respiratory viruses in an early stage of infection - namely in the nose – can play an important role during the COVID-19 pandemic.

CEBINA has previously identified the antihistamine drug azelastine as a potential anti-COVID-19 approach, demonstrating that azelastine has potent inhibitory activity against SARS-CoV-2 in *in vitro* infection models. This has been recently confirmed in a prospective, randomized, double-blind, placebo-controlled Phase 2 clinical trial initiated by CEBINA with its partner URSAPHARM (<https://www.researchsquare.com/article/rs-864566/v1>), demonstrating that a formulation identical to Pollival® (1mg/ml azelastine), URSAPHARM's widely available nasal spray containing the antihistamine drug azelastine hydrochloride, was effective in reducing the viral load in the nasal cavity of SARS-CoV-2 positive patients and rendered subjects COVID-PCR test negative earlier, compared to placebo.

“In addition to activity against SARS-CoV-2 and its variants (alpha, beta, delta), we have observed potent antiviral activity of azelastine against other RNA viruses, namely influenza and RSV under laboratory conditions. These data make us believe that azelastine will prove effective against emerging variants of SARS-CoV-2, including Omicron.” - commented Eszter Nagy, MD PhD, CEO, CSO and founder of CEBINA GmbH. “Witnessing how new variants such as Omicron are rapidly spreading and how SARS-CoV-2 is circulating together in the population with other major respiratory viruses with high disease burden and severity, such is

the case in this season with RSV, we now consider azelastine's broader antiviral effect of high importance. A nasal spray containing azelastine such as Pollival® has the potential as a widely available, easy to use and safe general anti-viral solution to protect against respiratory infections in an early stage".

Data on the broad anti-viral effect of azelastine are included in the recently published patent application filed by CEBINA<sup>1</sup>.

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#### **ABOUT CEBINA:**

CEBINA GmbH – Central European Biotech Incubator and Accelerator ([www.cebina.eu](http://www.cebina.eu)) is an Austria-based company committed to advancing entrepreneurship through creating and nurturing early-stage life science projects and companies to develop new medicines and cutting-edge technologies. CEBINA actively identifies academic projects with product development potential to create new companies. CEBINA is also pursuing its own research & development projects, in particular in the infectious diseases area and has initiated multiple R&D projects to fight the COVID-19 pandemic. CEBINA also offers office and laboratory facilities, in-house research, development, financing and management capabilities to early and medium stage biotech companies.

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<sup>1</sup> CEBINA GmbH patent application WO 2021/239943