New Belgian clinical trial performed by Artialis SA shows major and positive effect of food supplement in hospitalised patients with COVID-19

The Belgian clinical trial CHOPIN was coordinated by Artialis (CRDO, Liège, Belgium) and conducted between April and October 2021 in CHIREC hospital sites (Delta, Braine-l'Alleud, Ste-Anne/St-Rémi). The randomised comparative clinical trial was conducted with two different groups of patients hospitalised for COVID-19.

In addition to standard care, the first group received the dietary supplement Nasafytol®, consisting of turmeric, quercetin and vitamin D. The second group received vitamin D (equivalent dose of 800 IU), in addition to standard of care.

The study showed that in the group receiving Nasafytol®:

- there was a significant reduction in the number of patients hospitalised on day 7 and day 14
- there was a significant acceleration in recovery to a state of health which allowed a return home
- there was a significant increase in the number of patients discharged from hospital on day 7,
 with an improvement in the clinical score on day 7
 - no serious complications occurred (no ICU transfers or deaths)

Brussels/Liège, 31 March 2022. Belgium has a long history of excellence in clinical research. This is due to the quality of its research centres, the innovative and specialist expertise of its researchers and access to state-of-the-art medical infrastructure.

Turmeric, quercetin and vitamin D were already known to have antiviral, antibacterial and immunomodulatory properties. Therefore, the researchers wanted to know what positive effects the combination of these three substances could have - not only on the virulence of COVID-19, but also on the development of the associated pneumonia.

For this centrally organised study - which allowed for homogeneity - 49 covid patients were enrolled and randomly separated into two groups. All patients were over 18 years old and hospitalised with a severe form of the disease. In the first one, the 'Nasafytol® group', 25 patients received Nasafytol® for up to 14 days in addition to standard treatment. In the second one, the 'Vitamin D group', 24 patients on standard treatment received vitamin D (equivalent dose of 800 IU) for up to 14 days. Both groups had similar demographic characteristics in terms of age, gender, height, weight, ethnicity and BMI¹. In addition, both groups had a similar clinical score, based on the WHO² classification (4 vs. 4), and a similar CRP³ level (57 vs. 58). Thus, the two groups were comparable. The only difference was their vaccination status, with a higher number of vaccinated patients (at least one dose) in the 'vitamin D group' than in the 'Nasafytol® group' (9 vs. 2).

"For this study, we chose a combination of bioactive quercetin, a bioactive turmeric extract and vitamin D3, they help maintain the body's immune system and the effectiveness of the natural defences," says Prof. Yves Henrotin, founder and executive chairman of Artialis and professor at the Faculty of Medicine of the University of Liège. "By combining these three elements, we wanted to develop a

¹ Body mass index.

² World Health Organisation.

³ CRP or C-reactive protein is a protein secreted by the liver in response to inflammation or infection in the body.

natural preparation that would help patients with COVID-19. On the one hand, by reducing the risk of serious complications, and on the other hand, by reducing the number of transfers and avoiding overcrowding in ICUs as much as possible. These were the main factors we had to take into account during the pandemic. That is why we tested this combination (Nasafytol®), as an addition to the standard treatment and in line with the WHO recommendations for clinical studies in relation to COVID-19."

The proven added value of a supplement in addition to standard treatment in hospitalised patients with COVID-19

The results are unambiguous. The group who received Nasafytol® as a supplement to standard treatment showed significant progress for all evaluated parameters.

Firstly, this group showed a significant reduction in the number of hospitalised patients: a reduction of 59% on day 7 and a reduction of 73% on day 14, compared to the group having received vitamin D.

Secondly, among the patients who received Nasafytol® there was a significant increase of 82% in the number of patients discharged from hospital on day 7. In fact, 76% of them left the hospital on day 7, compared to only 42% of the patients in the 'Vitamin D group'. Hospital discharge was also accelerated in the group of patients receiving Nasafytol®.

Moreover, the reduction in the WHO clinical severity score for COVID-19 was significantly greater (50%) in the 'Nasafytol® group' than in the 'Vitamin D group' on day 7. This means that the patients who received the dietary supplement showed a more rapid improvement in their general condition than the 'Vitamin D group'.

Finally, there was a significant difference in the number of patients experiencing serious complications from COVID-19. In the 'Nasafytol® group' there were no complications, no transfers to intensive care and no deaths. However, in the 'Vitamin D group', 5 patients had serious complications: 4 patients were transferred to intensive care and one patient died.

"The number of patients remaining in the hospital decreased significantly, and the number of patients discharged from the hospital increased significantly because recovery was accelerated. In the end, no patient was transferred to intensive care or died", said **Dr Gérain, head of internal medicine at Delta (CHIREC hospital group)**. "We are delighted with these results, and with the fact that we can offer a supplement to standard care, which will not only shorten the duration of hospital admissions and save lives, but also significantly reduce the workload of hospital staff."

About Artialis SA/NV

Artialis was founded in 2010 by Professor Henrotin (University of Liège, Belgium). It is a unique Contract Research and Development Organisation (CRDO) offering preclinical, clinical and bioanalytical services to support the development of innovative products until they reach the market. Artialis offers its clients - active in biotechnology, pharmaceuticals, medical devices or food supplements - tailor-made solutions, from research and development to preclinical (in vitro and in vivo experiments) and clinical testing. Finally, Artialis offers a wide range of bioanalytical services with numerous clinical markers, some of which are already on the market.

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For more information on the CHOPIN study

Study ID on ClinicalTrials.gov: <u>NCT04844658</u>