

RECENTLY ISSUED NEW STUDIES

QUERCETIN: A POTENTIAL HELP TO MINIMIZE EARLY-STAGE COVID-19 RISK

Milan, 5th July 2021 – Quercetin Phytosome[®] supplementation, in combination with standard care, when used in early stage of COVID-19 could aid in improving the early conditions and help in preventing the severity of the SARS-CoV-2 infection. Moreover, it statistically shortens the timing of molecular test conversion from positive to negative. These are the results of two recently issued human studies¹, carried out starting from the volume of data produced in the last 15 months for quercetin: those data suggested that this polyphenol, whose properties in supporting respiratory health are scientifically proven, could be a potential adjuvant to manage early stage conditions of COVID-19.

Of course, in the global emergency due to COVID-19 it's definitively critical, thus required, to follow the guidelines provided by international and local Health Authorities. Social distancing, mask use, consulting the doctor if any symptoms occur are the strict and necessary rules everybody must follow. And it's important to remember that only drugs must be used in acute clinical situations. On the other hand, exactly with a view of supporting healthy prevention, it's also worth remembering that some botanical ingredients, like quercetin, have proven capacity to modulate immune and inflammatory responses in individuals suffering from respiratory discomforts.

"Starting from the mentioned evidences, we carried out a first prospective, randomized, controlled, and open-label study, in which in addition to standard care a daily dose of 1000 mg of quercetin Phytosome[®] was investigated for 30 days in 152 COVID-19 outpatients to disclose its adjuvant effect in treating the early symptoms and in preventing the severe outcomes of the disease – says **Prof. Dr. Ikram Ujjan**, **MBBS**, **PhD**, **Pro Vice Chancellor, Liaquat University of Medical and Health Sciences (LUMHS)**, **Jamshoro, Pakistan** - According to the results of this clinical research, the add-on therapy with quercetin Phytosome[®] has significantly reduced the need (-68.2%) and the length (-76.8%) of hospitalization, the need of non-invasive oxygen therapy (-93.3%), the progression to intensive care units (none versus 8 subjects) and the number of deaths (none versus 3 subjects). Globally considered, using quercetin Phytosome[®] as add-on therapy to standard care has reduced by 91.6% the days of hospitalization".

Quercetin, a flavonol not naturally present in the human body, is the most abundant polyphenol in fruits and vegetable and is widely used as a dietary supplement to boost the immune system and promote a healthy lifestyle. Quercetin is characterized by crucial pharmacological properties including broad-spectrum antiviral, antioxidant, anti-inflammatory and immune-protective effects, which allows it to be a potential candidate to support all unhealthy conditions where oxidative stress, inflammation and immunity are involved. These conditions include discomforts related to cardiovascular health, healthy-aging, bones and joint health, sport and physical activity, gut, and respiratory health².

The interesting results of the first study, led researchers to set up a second study to focus initial outcomes.

"In our 2-week, randomized, open-label, and controlled human study, we have enrolled 42 COVID-19 outpatients. Twenty-one have been treated with the standard of care (SC), and 21 with quercetin Phytosome[®] as add-on supplementation to the SC. Our main aims were to check virus clearance and symptoms and one of our primary endpoints was time needed to become negative at the RT-PCR for

¹ Di Pierro et al., Possible Therapeutic Effects of Adjuvant Quercetin Supplementation Against Early-Stage COVID-19 Infection: A Prospective, Randomized, Controlled, and Open-Label Study, International Journal of General Medicine 2021:14 2359–2366. https://www.dovepress.com/possible-therapeutic-effects-of-adjuvant-quercetin-supplementation-aga-peer-reviewed-fulltext-article-IJGM https://pubmed.ncbi.nlm.nih.gov/34135619/

Di Pierro et al., Potential Clinical Benefits of Quercetin in the Early Stage of COVID-19: Results of a Second, Pilot, Randomized, Controlled and Open-Label Clinical Trial, International Journal of General Medicine 2021:14 2807–2816.

https://www.dovepress.com/potential-clinical-benefits-of-quercetin-in-the-early-stage-of-covid-1-peer-reviewed-fulltext-article-IJGM ² Anand David AV, Arulmoli R, Parasuraman S. *Overviews of biological importance of quercetin: a bioactive flavonoid.* Pharmacogn Rev. 2016;10(20):84–89. doi:10.4103/0973-7847.194044)



SARS-CoV-2 – explains Francesco Di Pierro, Scientific & Research Department, Velleja Research, Milan, Italy - Our initial results demonstrated the beneficial role played by quercetin Phytosome[®] after only 1 week of add-on supplementation. In particular, the use of quercetin Phytosome[®] at the dose of 1500 mg/day for 1 week followed using 1000 mg/day for another week (corresponding to 600 and 400 mg of quercetin per day, respectively), has demonstrated to significantly increase the clearance of the virus, reduce the symptoms occurrence and improve disease biomarkers. An enlargement of this study is currently ongoing".

"Quercetin has diverse health benefits and has been widely used as dietary supplement to boost body's immune system and keep healthy lifestyle. Tackling the COVID-19 in the early-stage of infection is very crucial to minimize the severity of the disease. The results of the two pilot clinical studies are very encouraging and deserve further clinical explorations in the context of COVID-19. Quercetin is a safe, affordable and worldwide available agent – says Dr. Amjad Khan, Postdoc/DPhil/M.Sc (Oxford University), University of Health Sciences, Lahore, Pakistan".

Like many botanical extracts and natural compounds, quercetin is provided with poor water solubility. As a consequence, it is barely bio-absorbable and that decreases its potential effectiveness. For optimal bio-absorption, natural products must have a good balance between hydrophilicity for dissolving into the gastro-intestinal fluids and lipophilicity to cross cell's lipidic bio-membranes. In both the mentioned studies it has been used Quercefit[®], Indena's quercetin in a delivery-food grade system with sunflower phospholipids (Phytosome[®]), which has been proven to increase its oral absorption up to 20-fold. Phytosome[®] is Indena's proprietary 100% food-grade biomimetic delivery system, the result of a wide experience and deep knowledge in product and process research.

"As an Italian company, we are very proud to be part of such important international studies focused on a signature ingredient of Indena, such as quercetin phytosome[®].- says **Stefano Togni, Corporate Director for Business Development and Licensing of Indena S.p.A.** - This is another step of the work Indena has been committing to since one hundred years, in order to support scientific research in the field of botanical active ingredients. Company's continuous investment in innovation and design of proprietary technologies for the quality, safety and efficacy of ingredients, are the pillars on which Indena has built its leadership in the botanical sector as well as its inspiration for the future business".

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Indena is the leading company dedicated to the identification, development and production of high quality active principles derived from plants, for use in the pharmaceutical and health food industries. Backed up by a century of botanical experience, the company owns 100 patent families, has published more than 1000 scientific studies and cooperates with the world's most prestigious universities and private research institutions. Indena employs over 900 staff, investing a significant amount of its annual turnover in research, making this activity the key to its success. Headquartered in Milan, Indena has 4 production sites and 5 international branches throughout the world and manages sales in more than 80 countries. The company's experts communicate and interact constantly with the major international regulatory authorities and cooperate on the update of all the main pharmacopoeias.

Today Indena has further expanded its CDMO offer encompassing new services. In particular, a kilolab to handle semisynthetic and total synthetic APIs that require high containment (OEL of 20 ng/m³), a new multipurpose GMP pilot plant, a multipurpose fermentation suite and large-and-mid size spray dryers working with organic solvents. Find more on <u>indena.com</u>