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Strategic use of Lelmmune-T for control of COVID 19 pandemic

Lelmmune-T is an extract of tomato in edible oil and contains at least 418 µg bioavailable β-carotene dissolved in edible oil, is a Nutraceutical listed at No. 164 in Schedule VI of the “Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016” (“The Regulation”, hereafter). It may further contain permitted additives.

Lelmmune-T is not a medicine of any kind. Drugs and Cosmetics Act is not applicable nor any standards applicable to medicine are applicable to Lelmmune-T.

This product comes under the domain of “Clinical Nutrition” which is very closely connected with therapy of any disease by any school of medicine and is not out of scope of practice for medical practitioner of any school-of-medicine, whether Allopathic or Ayush, because unless the clinical nutritional status of a patient is broadly balanced and responsive, medicines do not work. For example prescribing information of Metformin, an allopathic drug, is that “Metformin hydrochloride tablets as monotherapy, is indicated **as an adjunct to diet and exercise** to improve glycemic control in patients with type 2 diabetes mellitus.” Please note the word “adjunct” which keeps “**diet and exercise** to improve glycemic control”, the clinical nutrition parameter as primary factor and Metformin is an adjunct to it. Similarly, prescribing information for Atorvastatin is: “Atorvastatin calcium, Lipitor, tablets are a prescription medicine that is **used along with a low-fat diet**”, wherein “that is **used along with a low-fat diet**” is a clinical nutrition related parameter, without which Atorvastatin would not remain efficacious. In Ayurveda, along with medicine, prescriptions of what to eat and what not to eat are equally important recommendations. And such Clinical Nutrition related article mostly are foods and their manner of consumption. Hence, although clinical nutrition related articles are not medicines, they are very much within the scope of EVERY school of medicine, although it may be food or an article derived from food source.

Hence, LeImmune-T can very well be appraised by every school of medicine along with their own relevant medicines; but by applying Food Safety and Standards Act, 2006 and regulations under them. In this case, LeImmune-T, as noted above, is a nutraceutical under The Regulation and its health claim is to be appraised in the context of regulation (8)(i)(ii)(v)(v) recited in The Regulation.”

It is our well considered understanding in the context of COVID-19. based on above information, is as follows:

Being non-specific in its action against a pathogenic virus / being able to kill ANY virus that infects a cell, it is clear that **novel coronavirus is also included** within the capability of the Natural Killer Cells mediated immune system to detect and destroy; that too during the first critical hours of exposure to the new coronavirus. The greatest benefit is: the infecting novel coronavirus gets destroyed before it has an opportunity to multiply, start proliferation within the body of the infected person and develop disease in him; and chain of infection stops at such a person. Additionally, since the infected person’s Adaptive Immunity system has got exposure to the novel Coronavirus in this process, it will surely develop antibodies against the novel coronavirus, making him immune to novel coronavirus as if he is injected with a proper vaccine against the novel coronavirus. Thus, for all persons who shall have Natural Killer Cells activity at its optimum, whenever any such person gets exposed to novel coronavirus, instead of developing the disease, they will develop antibodies (Adaptive immunity) against the novel coronavirus.

However, in Innate Immunity compromised persons, this destruction of the virus infected cell does not occur. Although Adaptive Immune System of the body responds to such an exposure of novel coronavirus to make antibodies against the same, it takes at least 5-6 days to become effective; and in that interval, with very low resistance from the host, the novel coronavirus proliferates fast, spreads in the body manifesting the disease. Fate of the patient depends on whether the whatever level of Innate Immunity is present in combination with newly developing anti-bodies combine together and succeed to overpower the virus that has already spread in the body to achieve recovery or not. The experience is, aged amongst the Innate Immunity Compromised persons usually lose the battle. Thus, if Natural Killer Cells are in state of optimum activity, the initial infection from a virus ends at the site of the cells infected by them itself along with destruction of that cell by Natural Killer Cells, the person will not even know that he has been infected by the virus, and there is no question of any detectable spread of the virus in the body; on the contrary, after 5-6 days, he will also have Adaptive Immunity developed in his body as if he is vaccinated – a sort of Natural vaccination. Thus depending on what is the level of activity of Natural Killer Cells/Innate Immunity in a person at the time of infection from Coronavirus, result of infection will range

from (a) no sickness and development of Adaptive Immunity, (b) mild sickness like fever and early recovery, (c) moderate sickness with fever, cough, breathing difficulty followed by recovery, (d) intensive sickness with fever, cough, breathing difficulty followed by Intensive Care Unit admission followed recovery after a long time and after intensive suffering,(e) intensive sickness with all above symptoms leading to ventilator support and low probability of recovery.

Ultimately, it becomes clear that the status of Innate Immunity at the time of infection determines whether the disease will follow and how will it progress.

It is clear that keeping the innate Immunity always at its optimum activity is necessary for safety against any pandemic, including COVID-19.

Thus, Innate Immunity compromised persons are at biggest risk from COVID_19.

However, although Innate Immunity is compromised in elderly and other categories of compromised persons, it is restored by β -carotene supplementation_(Hughes,1999, Santos et al, 1996).

The group of Innate Immunity compromised persons includes persons of all ages who are diabetic, hypertensive, heart patients, chronic kidney disease patients, heart patients, patients undergoing chemotherapy, cancer patients, Children below 10 years of age and the persons whose duties are subject to strenuous overwork, those working closely with patients infected with communicable diseases such as Doctors, nurses, ward-boys in hospitals and those whose diet as a regular feature does not include green leafy vegetables and fruits that provide enough quantity of beta carotene. Strenuous physical exercises/sports also lead to depression of Innate Immunity.

Mandatory Need of Innate Immunity Booster as part of any epidemic/pandemic management program: It is this group of persons which is most susceptible to develop disease from infection of the novel coronavirus, they remain infective for a long time and serve to keep the chain of infections intact and progressing.

Since social distancing measures are not being practiced scrupulously by the population at large, and there is no way that it can be enforced either, until the vaccine reaches the entire population, our choice is, either:

- (a) to be a passive spectator and allow the situation to drift to continuing chain of infections through the Innate Immunity compromised people which is leading to everyday increasing number of new infections leading to flooding the hospital capacities to full and leaving the infected Innate Immunity compromised patients

to their fortune; or

- (b) to take additional pro-active step to reduce their risk of infection from novel coronavirus by providing them Natural Killer Cells mediated Innate Immunity Booster.

It is obvious that this is a great lacuna; which will be filled up by LeImmune-T, a clinical nutrition based product, a nutraceutical, which has above health claim supported by significant scientific agreement and the food regulation; and should be immediately put to use to rapidly control spread of novel coronavirus.

Improving Innate Immunity of ALL Innate Immunity compromised persons has not been addressed so far in anti-Covid-19 program in India as well as elsewhere. It is obvious that if Innate Immunity of the compromised persons is improved back to its optimum level, number of persons in infective stage of COVID-19 shall do down drastically significantly weakening the chain of infection; ultimately breaking the chain altogether .

To end a Pandemic by breaking the chain of infections fast and building up of “Herd Immunity” without sacrificing the Innate Immunity Compromised population: Most important contribution LeImmune-T will make to anti-covid-19 program is **breaking the chain of infections** which has become impossible due to poor adherence of the vulnerable population in containment areas to social distancing requirements.

Providing LeImmune-T to ALL Immune Compromised persons in a containment area or an area where the infection is spreading will bring in the benefit that the activity of their Natural Killer Cells will restore to normal level in about 15-30 days (depending on Vitamin A status, because in Vitamin A deficient persons, beta carotene will first get converted to Vitamin A until the stores reach to optimum and then only beta carotene will become available for the function of boosting activity of Natural Killer Cells.) the infecting novel coronavirus gets destroyed before it has an opportunity to multiply, start proliferation within the body of the infected person and develop disease in him; and chain of infection stops at such a person. Additionally, such persons would develop antibodies also as if they are vaccinated.

- The resulting immunity against novel coronavirus in Innate Immunity Compromised persons, which are the main links in the chain of infections, would break the chain of infections; and would bring control of spread of the novel coronavirus.
- Combination of the normal Innate Immunity persons and the Innate Immunity Booster taking Innate Immunity compromised persons would lead to development of a sort of “Herd Immunity” without getting infected with the new coronavirus or with getting infected but without developing the disease due to improved activity of Natural Killer Cells, which will help ending the pandemic.

- The benefit is: there shall be no need to revert back to lockdown in any part of the country, no need of running and expanding hospital capacities for accommodating everyday increasing number of patients, sharp reduction in expenses on the infected patients; the economic benefit of which is several times more than cost for implementing providing Lelmmune-T to compromised persons through government channel to those who are economically deprived, and to educate and by a government promoted campaign on mass media, recommend this product to those who can afford to purchase the same.
- As and when vaccine comes, this should also be given additionally to make the protection absolute.
- Even after the vaccine comes, there is likelihood that its antibodies may be limited to:
 - only up to 6 months (<https://www.msn.com/en-in/health/familyhealth/immunity-to-coronavirus-could-only-last-six-months-study-finds-casting-fresh-doubt-on-ministers-plans-to-give-survivors-immunity-passports/ar-BB14u7Ya?ocid=spartanntp>),
 - Investigation of Dr. Katie Doores of King's College, London(<https://www.kcl.ac.uk/news/covid-19-antibodies-decline-over-time>). on patients recovered from Covid-19 is very pertinent, according to which the adaptive immunity developed from infection of Novel Coronavirus remained at least up to 12 weeks and wane thereafter. Nothing different is expected to happen from a vaccine developed from the same virus. Dr. Katie further says:
 - “We also need to know more about the titre of antibody that is required to prevent re-infection in humans. We can draw some information from animal studies but it is important to study individuals who have been previously infected with SARS-CoV-2 to see whether they become re-infected and if so, whether the severity of disease is reduced.”
 - Antibodies are just one of the ways in which the body can fight a virus such as SARS-CoV-2.
 - Further studies are needed to determine the longevity of the antibody response and what level of antibodies is required to protect against re-infection.
 - In summary: Contrary to general belief, Vaccine (Adaptive Immunity) is not going to be the final and permanent answer against Novel Coronavirus. Innate Immunity cannot be ignored.
 - On this background, Lelmmune-T remains the most reliable and well founded in robust science as a first line action against a pandemic; vaccination is only a Second Line action which cannot replace the need of an Innate Immunity

Booster: LeImmune-T is only currently available Innate Immunity Booster. .

- Further: if a person is receiving LeImmune-T also before the vaccine arrives, it is very much possible that Natural Killer Cells are also now seen to have “memory function” that provides Adaptive Immunity too; and their presence may ensure that either the anti-bodies produced by vaccine last longer or their combined protection may last longer than the vaccine-mediated antibody protection alone.
- Hence, LeImmune-T shall be relevant in all situations: before vaccine arrive, with vaccination and also after vaccination period also.
- Above measure will protect the Innate Immunity compromised persons, and impliedly the entire population, from not only novel coronavirus, **but also from any mutations of Novel Coronavirus** and also ANY other pathogenic virulent virus that may come in future, which will not spread at all, if consuming LeImmune-T is made a part of daily routine.
 - The speculation of likelihood of occurrence of mutations in Novel Coronavirus that would make currently developing vaccines ineffective against the new strain have not remained a figment of speculative imagination.
 - The New Coronavirus Strain Found In Malaysia Is TEN TIMES More Infectious

TIMESOFINDIA.COM | Last updated on - Aug 17, 2020, 11:04 IST

https://m.timesofindia.com/life-style/health-fitness/health-news/the-new-coronavirus-strain-found-in-malaysia-is-ten-times-more-infectious/amp_etphotostory/77585251.cms?ps=1

Dr Noor Hisham Abdullah who is the health director-general Datuk shared on Facebook this Sunday that this calls for greater precautions as the Covid-19 virus with the D614G mutation has been detected in Malaysia. According to the post, the mutation was first detected in the month of July, and he feels that studies will most likely reveal that the existing vaccines in work will be rendered ineffective against the mutation.

Dr Anthony Fauci, the director of the National Institute of Allergy and Infectious Diseases said that the new mutation may speed the spread of the coronavirus. It may also make the existing studies on the vaccine ineffective and incomplete.

LeImmune-T will take care of this as well as any other mutations that may have occurred that would not be affected by the vaccines in current pipeline.

“Innate Immunity Booster” vs. “Immunity Booster”: Here it is necessary to be aware that

there are several “Immunity Boosters” available in the market that contain Zinc, Vitamin A, Vitamin C, Vitamin D, Vitamin E, Selenium etc., but none of them are “Innate Immunity Boosters”, none of them seen in literature to have a significant scientific agreement that they work through Natural Killer Cells mediated improvement in Innate Immunity. To be accurate, they are “Adaptive Immunity Boosters”; i.e. they will boost action of adaptive immunity that is already developed in the form of antibodies in their body; for example they may have antibodies for small pox, typhoid, rabies etc. It is obvious that Innate Immunity compromised persons would not have antibodies for novel coronavirus; hence, such “Immunity Boosters”, which do have their own importance and value in immune system, are not useful to reduce the risk of infection from novel coronavirus unless Innate Immunity Boosters are consumed as first line measure to be accompanied/ followed by the second in line “Immune boosters”.

If indeed any products described as “Immunity Boosters” have scientific evidence that they improve the activity of Natural Killer Cells in Innate Immunity Compromised patients they should be labeled as “Innate Immunity Booster” and they are also eligible for use the way we are suggesting use of Lelmmune-T.

Promoting use of Lelmmune-T for control of Covid-19 Pandemic will promote fast recovery of economy after lock-down and fast improvement in Indian economy:

- Presuming that persons having co-morbidities is about 20% of Indian population, Lelmmune will have to be manufactured for 26 crore people. This, approximately works out to 2.6 crore kg = 26000000 kg = 26000 tons of tomato will have to be processed for one month supply. Thus annually 3,12,000 tons of tomato will have to be processed per year. <https://www.agrifarming.in/tomato-profit-per-acre-cost-of-cultivation-yield-in-india> informs us that annual tomato production in India is **20515000 MT**. Thus, demand of India can be satisfied; which will generate economic activity in rural areas, tomato processing industry that is around the rural centers and a further additional processing industry that shall make Lelmmune-T.
- Once the anticipated effect of breaking chain of infection is confirmed, there shall be demand from outside India too, which could be 5 times the demand of India, and total demand shall be $3,12,000 * 6 = 18,72,000$ tons i.e. about 9% of annual production in India. If this demand generates, it is most likely that farmers shall supply this additional demand by bringing that much additional area under tomato cultivation. This will recover the battered rural economy, the tomato processing industry and further Lelmmune manufacturing Industry and manpower working in these sectors.
 - This is estimated to generate a turnover due to Lelmmune-T of about 5.6 lakh crore; 1/5 th of which may come from exports.
 - India’s total revenue loss on account of COVID-19 is estimated to be about 10

lakh crore.

- Thus, 50% of this loss shall be recovered by this product alone, which shall be a sumptuous bonus on the total control on their pandemic in relatively short time.

This is in addition to saving on the cost of treating the patients. which to be very conservative is Rs. 10,000 per patient only on PPE kits and disposables when admitted in a hospital. Number of patients currently in hospitals as on 17th June 2020 is about (3,55,060 confirmed - 11,923 deaths - 1,87,718 recovered) = 1,55,419; and their per day expenditure is $1,55,419 * 10000 = 155$ crore i.e. Rs. 4,650 crore per month. This expense shall increase, if current rate of fresh infections per day remains same, at least by about $10,000 * 10000 = 10$ crore per day or Rs. 300 crore per month. The total going to Rs. 4950 crore per month presuming that there shall be no further increase in per day rate of fresh cases.

- On 20th June, 2020, the Central Government has given directive that the cost of treatment of 60% of beds in private hospitals should be 30% of what were being charged so far for COVID-19 patients. However, this 30% is also not small enough to be affordable to a common man. They:

“----- have been capped between Rs 8,000 (non-NABH accredited hospitals) and Rs 10,000 (NABH accredited hospitals including entry level facilities) a day for an isolation bed, Rs 13,000-15,000 a day for a bed at an intensive care unit (ICU), and Rs 15,000-18,000 a day for an ICU bed with ventilator. Until this order was issued on Saturday evening, the fee for an isolation bed in Delhi was Rs 24,000-25,000 a day. For an ICU bed, it was Rs 34,000-43,000 a day, while an ICU bed with ventilator was Rs 44,000-54,000 a day”.

- Presuming that out of the 20% co-morbid Indian population, which is major Innate Immunity compromised population, a 10% of them (2.6 crore) is the only population which lives in the containment zones and cannot afford to buy Innate Immunity Booster, Government may consider supplying them the same free of cost. In our preliminary estimate of this will cost is Rs. 260 crore per month for at least 3 months within which it could be fairly expected for the infection progressing chain in the containment area be broken. By spending this Rs. 260 crore per month in containment areas, it may be possible to decline current expense of Rs. 4950 crore very near to zero.

Total control on Covid-19 within next few months by co-ordinated use of LeImmune-T until the vaccine reaches the entire population followed by the LeImmune-T + vaccine

to rule out even the potential mutant strains of the Novel Coronavirus will give confidence to the industries pulling out of China to come to India making the “Make in India” program exceedingly successful; that is very big additional benefit. That may make India third most prosperous economic power within a couple of years; making the dream of India a 5 trillion dollar economy, or even more, a reality far ahead of the contemplated deadline.

Other aspects of Lelmmune-T application:

- **Protecting India against Biological Warfare:** Rather, in view of threat of biological warfare by rough countries or terrorists as a continuing potential threat, providing access to all people with Lelmmune-T should be a part of National Disaster Management Program for all the time to come. Such episodes may involve more virulent pathogens spread over large geographical areas, people will fall pray to the danger very fast; and thereafter even if you know an Innate Immunity Booster might check further spread, there would be no time to produce it at scale required for entire population and it may further take about 15 days to develop from the day the booster is introduced in consumption.

From all angles, we invite you for an immediate interaction on this issue so that you will be in a position to make recommendations to the Government of India to make sue of this product with immediate effect for anti-covid program.

We ourselves are an R&D company, not manufacturers; but we have contact through networking with many manufacturers who have an ability to take up manufacturing of this product and their total supply may match with the requirements for this program. We would hand-hold then for technology transfer and production and supply of this product.

The earlier this is done, the lesser will be suffering to people, doctors, nurses and hospital staff and administration coping with the huge problems thrown by Covid-19.

If you are not the proper persons to look into this matter, please route it to the appropriate people with whom we can take this interaction further.

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