Novel molecule shows promising results against COVID-19

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Committed to the battle against COVID-19 from the outset of the pandemic, the Center for Genetic Engineering and Biotechnology (CIGB) made available to the national health system not only its capacity to produce Recombinant Alpha 2b Human Interferon, but also analyzed, and submitted for the consideration of Cuban medical specialists, research linked to the development of new molecules, which was taking place in this scientific institution affiliated with the BioCubaFarma state enterprise group.

One of the examples, widely disseminated in the media in recent weeks, is the medication CIGB-258, with verified results in clinical trials suggesting that it could have a positive impact in treating COVID-19 patients at a certain stage of the disease.

To share experience gained thus far in Cuba with the use of this product and the properties, that supported its incorporation in the fight against the new coronavirus, Dr. Gillian Martínez Donato, CIGB researcher and manager of this scientific project, answered the following questions for Granma.

What is the CIGB-258?

It is an immunomodulatory peptide, derived from the cellular stress response protein, known as HSP60. The molecule was designed using bioinformatic tools and is obtained by chemical synthesis.

It has functions associated with regulation of the immune system. This protein increases its presence during viral infections and inflammatory processes. Peptides (protein fragments of low molecular weight) derived from HSP60 can constitute a danger signal for the immune system and induce a response to eliminate pathogens.

Other peptides from HSP60 have an immunoregulatory function and, once the pathogens are eliminated, these peptides contribute to regulating the extent of the inflammatory response. CIGB-258 was designed to essentially

activate the mechanisms that control and reduce inflammatory processes.

This peptide has been shown to be safe with evidence of efficacy in Phase I clinical study in patients with rheumatoid arthritis, by reducing the clinical activity associated with that condition, including synovitis and edema in patients' hands.

This evidence is associated with reduced inflammation, caused by the immune system in this type of illness. It was also corroborated that, in these patients, the concentrations of inflammatory cytokines (molecules produced by the immune system) decreased. A Phase II clinical study is currently underway in 187 patients with rheumatoid arthritis, and the results will be available by the end of 2020.

Why was the use of CIGB-258 with COVID-19 considered?

SARS-COV-2 infection has spread rapidly throughout the world. While 80% of those infected experience mild flu-like symptoms or no symptoms at all, 20% may evolve to serious or critical condition.

Statistics show that, on average, 80% of critical patients die and the fundamental cause is acute respiratory distress. This respiratory distress is caused by an exaggerated inflammatory reaction by the immune system to infection with the virus. The scientific literature calls this type of reaction a "cytosine storm", since these molecules, secreted by cells of the immune system, abruptly increase in number.

Such a pattern of hyper-response can trigger cardiovascular collapse, multiple organ failure and death in patients with COVID-19.

Taking into account CIGB-258's mechanism of action, linked to the regulation of inflammation, and results in clinical studies which demonstrated the safety and evidence of reduction of joint and systemic inflammation, the CIGB submitted to the State Center for the Control of Medicines, Equipment and Medical Devices (Cecmed), a request for its use in confirmed COVID-19 patients in serious and critical condition.

This request was approved, and thus its use in our country began.

What results have been achieved with this medication?

As of May 5th, a total of 31 patients had received therapy with this peptide, 12 began therapy in serious condition and 19 critical. The survival rate for patients in serious condition treated with CIGB-258 was 92% and 73% for patients in critical condition. Overall, the survival rate for patients in these two categories was 81%.

These results are really very encouraging, especially because international reports have reported that the survival rate of COVID-19 patients in critical condition does not exceed 30%. We continue to accumulate evidence to draw conclusions about the effectiveness of CIGB-258 in treating COVID-19.