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THE THERAPEUTIC EFFECT AND EXPECTED ECONOMIC IMPACT OF ITV-1

Written by Dimitar Savov

ITV-1's mechanism of action characterizes it as a powerful immunomodulator, whilst, in its composition, the drug is a protease inhibitor; in these two properties, it is intended as a powerful anti-retroviral agent. ITV-1 was patented in the U.S. for the treatment of HIV/AIDS, after which it has successfully completed Phase I, Phase II, and Phase III – a clinical trial on human patients. The clinical trial was conducted on 31 patients at the *Specialized Hospital for Active Treatment of Infectious and Parasitic Deceases "Professor Ivan Kirov"*, Sofia, all of whom were in the advanced stage of AIDS, i.e., on average having less than 550 CD4+ cells per cubic millimeter. To summarize the results of the clinical trial in one simple sentence, the viral load of the patients was reduced to 0 and the immune cells were increased by 180 units per milliliter of blood on average, which proves an extremely good therapeutic effect; a more comprehensive information regarding the clinical trial may be found in the [Final Report](#).

Outside the clinical trial, ITV-1 was administered to over 50 volunteers suffering from AIDS, all cases resulting in the complete destruction of the viral load and significant increase in immune cells. The case of a young 22-year-old woman in the advanced stages of AIDS is a very indicative example of the therapeutic effect of ITV-1; after undergoing two treatment cycles of 16 injections of ITV-1 and seeing that the viral load in her bloodstream is below level of detection, her boyfriend and her decided to take a risk in order to have a baby without first testing the viral load on a DNA level. Now husband and wife with two children – a boy and a girl, the entire family have done multiple tests in the past 5 years, with the woman continuing to show no AIDS viral load with the rest of the family being completely healthy as well. This indicates that ITV-1 attacks the virus not only in the blood, but also at the DNA level, meaning in depth.



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Since recent scientific research shows that some types of cancer are caused by a virus, and other types by bacteria, we have tested ITV-1 on several hundred volunteers suffering from various types of cancer, such as uterine cancer, prostate cancer, pancreatic cancer, colon cancer, lung cancer and leukemia. When applied to volunteers in the first stages of the disease, Stages I and II, and before the start of chemotherapy, ITV-1 shows over 80 percent efficacy and curative effect. In cases of prostate and uterine cancer, ITV-1 has shown over 50 percent success rate (curative effect) even on people in Stage IV of the disease. This is due to the fact that as an anti-retroviral drug, it attacks the cause of cancer and activates the patient's bone marrow to produce lymphocytes and rebuild the human immune system, which is significantly compromised in such diseases. It should be noted that ITV-1 is generally not compatible with chemotherapy, as chemotherapy is a suppressive agent and attacks both diseased and healthy immune cells, making the two treatment methods incompatible.

In two other cases, ITV-1 was applied to volunteers with chronic hepatitis B and C who had heavily loaded liver with indicators of an initial stage of cirrhosis. In both instances, the cirrhosis was cured and the liver function of the patients was completely restored; it can be said that both volunteers are clinically completely healthy for more than 10 years. Another important case was a patient with a very severe degree of tuberculosis, treated with the latest available treatments in the Military Medical Academy of Sofia (one of the most modern hospitals in Europe) without success and discharged from the hospital with a doctor's prognosis for the worst expectations (fatal case). After two treatment cycles of 16 injections with ITV-1, the tuberculosis was completely cured and for more than 8 years the patient has been in extremely good health. ITV-1 has also been administered to a patient with *Staphylococcus aureus* - a severe staphylococcal infection in a very advanced stage with severe purulent wounds on his legs, who had tried all possible antibiotics and other treatments without any effect. Despite the fact that bacterial infections are one of the most severe and persistent diseases, he was completely cured after undergoing one treatment cycle of 16 injections of ITV-1,



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It should be noted that ITV-1 was also applied on some pets, dogs and cats, in a veterinary clinic in Sofia, Bulgaria. Cats and dogs suffer from diseases mostly similar to humans' diseases and carry an important emotional role as they are often considered as family members, not just pets. A treatment for ITV-1 requires much lower dosage for cats and dogs and a shorter treatment cycle. A significant case was that of a dog operated for uterine cancer that had afterwards developed significant abdominal metastases: after only 3 injections of ITV-1, in around 30 days the metastases had fully disappeared and the abdominal area had completely recovered. It has also been applied successfully on two dogs who were cured from canine distemper, which is highly contagious and fatal. Once the factory is ready, NIKA intends to do further research on the applicability of ITV-1 as a low-cost solution to currently incurable deadly diseases in pets.

OUR PHILOSOPHY AT NIKA PHARMACEUTICALS, INC. IS TO CREATE AND DEVELOP DRUGS THAT NOT ONLY HAVE A GOOD THERAPEUTIC EFFECT, BUT THAT ARE ALSO AFFORDABLE AND WITHOUT SIDE EFFECTS. ITV-1 ADHERES TO THOSE CORE PRINCIPLES, AS IT HAS SHOWN LACK OF SIDE EFFECTS AND SIGNIFICANTLY LOWER COST COMPARED TO CURRENTLY AVAILABLE THERAPIES FOR AIDS, CANCER, AND HEPATITIS.

For example, modern ART against AIDS cost an average of more 36,000 USD per year¹ and require continuous administration while the patient is alive, which means that over time such treatments reach between 300,000 and 400,000 USD per patient; in comparison, the retail price of ITV-1 will be 3,300 EUR (around 3,600 USD) for 16 injections, which makes a complete treatment consisting of two 16 injection cycles of ITV-1 to cost 6,600 EUR (around 7,200 USD) per patient. Accordingly, ITV-1 is affordable, as it is dozens of times cheaper and more effective that

¹ McCann NC, Horn TH, Hyle EP, Walensky RP. HIV Antiretroviral Therapy Costs in the United States, 2012-2018. *JAMA Intern Med.* 2020;180(4):601–603. doi:10.1001/jamainternmed.2019.7108



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previously used antiretroviral therapies. This is extremely important for a number of countries, especially in Africa and some parts of Asia, which cannot afford at the government level to provide the currently expensive therapeutics for these significant life-threatening diseases to all patients. It is substantial at an individual level as well to those suffering from AIDS who are reluctant to enroll in government programs in fear of stigma, who will be able to afford treatment with ITV-1 on their own.

In conclusion, we can say that ITV-1 is a medicinal product, a life-saving drug, which will have a significant place in the fight and treatment of the life-threatening diseases listed above. It can be applied both in conjunction with modern protease inhibitors and modulators, or as an independent therapeutic agent. It is a significant product that will not only help improve the life and health of millions of people, but will also lessen the economic burden on government healthcare agencies.

About Nika Pharmaceuticals, Inc.

Nika Pharmaceuticals, Inc. (NIKA) is a pharmaceutical company, specializing in the treatment of HIV/AIDS, Hepatitis B and C, Rheumatoid Arthritis, Cancer, Diabetes, and all diseases, for which strengthened cell immunity is of vital importance. NIKA's intellectual property includes six drugs in injection form – two of which have successfully undergone clinical trials with good treatment results – four drugs in tablet form, and eleven dietary supplements. NIKA's goal is to not only achieve corporate profits, but to provide better and easier access to life-saving medicinal drugs and useful dietary supplements. Find more on www.nikapharmaceuticals.com.

Forward-looking Statement:

This document contains forward-looking statements. Certain statements, other than purely historical information, including estimates, projections, statements relating to our business plans, objectives, and expected operating results, and the assumptions upon which those statements are based, are "forward-looking statements." These forward-looking statements generally are identified by the words "believes," "expects," "anticipates," "intends," "strategy," "plan," "may," "will," "would," "will likely result," and similar expressions. Forward-looking statements are based on current expectations and assumptions that are subject to risks and uncertainties which may cause actual results to differ materially. Our ability to predict results or the actual effect of future plans or strategies is inherently uncertain.