

Salvogene SARS-CoV-2 Task Force: New C-19 Vaccine and Medication Advisor Tool

KEYNOTE

Dear Premium Customers,

Gam-Covid-Vac is a joint project between the Russian Ministry of Defense and the internationally little-known Gamaleya Research Institute of Epidemiology and Microbiology. Starting on 20th August, the world's first vaccine against Covid-19 will be widely distributed for use on the general public. The first large-scale trials began some time ago on thousands of military personnel as well as doctors and teachers. The decision has now been taken to extend it to the entire population.

This project has put the spotlight on the world's first nationally approved corona vaccine. It is based on human adenovirus vectors into which parts of the SARS-CoV-2 gene have been integrated. The recipient is injected not with an inactive form of

the pathogen but instead a formulation that induces an immune system response similar to that provoked by the coronavirus.

It is claimed that neither the vaccine nor the protein produced after the antigen has entered the cell can cause Covid-19. In our view, this is not guaranteed, as Phase 3 of the approval procedure has been bypassed. This is, however, the most important phase, which involves tens of thousands of volunteers being tested over a period of several months. Furthermore, the results are usually published in advance in the main scientific media and thus made available to other scientists. This has not happened in the case of Gam-Covid-Vac. So unfortunately, we in the SARS-CoV-2 Task Force have relatively little information about the vaccine. However, we expect that this medication could soon become available on the black market and therefore warn our clients not to use it under any circumstances!

There are currently more than 100 candidate vaccines in the pipeline, and four of them have now entered the final Phase 3. Three of them are under development in China and one in the UK. The Russian project is not the only one we need to remain cautious about. In other countries too, a lot of money has been invested in vaccine production via the stock exchange, and research has been very much accelerated. We have already stated our belief on several occasions that, despite the urgency of producing a vaccine as soon as possible, speed is being put before safety, and some of the standard approval phases have simply been skipped over. We expect considerable side effects from the various vaccines and drugs in the medium term and will support our clients as best we can in an advisory capacity.

We expect a more or less "officially" approved vaccine to become available in January or February 2021. Apart from potential undesirable side-effects, it will also not be possible to say with any certainty how long immunity will last, as there has not been time to pursue this scientifically. From a social and epidemiological point of view, it makes sense to make vaccines

part of the solution for society as a whole, but it is a different matter for the individual situation of each person.

As we see it, our task here is to clarify meticulously and systematically for each of our clients over the next few months or even years whether and to what extent a particular vaccine can be of benefit to which individual and at what point in time.

The importance of the individual's state of health

In order to achieve this, we must of course weigh up the possible side-effects of the vaccine against the individual's state of health and then draw conclusions as to whether it might not be better to wait for the next vaccine to come along. This has to be an ongoing process, because any advice we give has to take two perspectives into account. On the one hand, there is the high dynamic rate at which vaccines and drugs are being developed. Yet on the other hand, the health status of the individual is also undergoing constant change. It is only when the two aspects are considered in combination that appropriate recommendations can be made.

We will be looking carefully at the following points on the vaccine side of the equation:

- The basis on which the vaccine types were developed in order to evaluate the possible use of the vaccine
- We essentially distinguish between four different types of vaccines:
 1. So-called "killed vaccines" based on the inactivated coronavirus itself; these are mostly approved for military use and originate from India or China
 2. Selected viral proteins are used instead of the whole virus, a prime example being the U.S.-based company Novavax which attaches proteins to tiny particles of the virus; they

have already announced some successes in trials with both monkeys and humans.

3. Another approach is vector vaccines. They use the envelope of other viruses to introduce coronavirus genes into the body and induce an immune response. For example, the British-Swedish company AstraZeneca uses adenoviruses, as does the above-mentioned vaccine developed by the Russian Ministry of Defense.
4. Finally, the most modern technique is DNA or RNA vaccines, which do not use any virus components at all, but channel parts of the virus's genetic information into the body's cells. The cells are then stimulated to produce their own viral proteins which do not cause illness but instead prepare the immune system for an encounter with the real virus. We are working on the assumption that this approach is the one that will cause the fewest undesirable side-effects. BioNTech and CureVac based in Germany as well as Moderna in the USA, deserve particular mention in this regard.

Each of these four types has its advantages and disadvantages, and we will advise accordingly on whether and how suitable each option is for each client.

For each individual client's health circumstances, we will consider the various factors that determine the extent to which the medication can be effective at all and what sort of side-effects are to be expected. These factors include:

- The Pharmaco Genetic Profile from our Premium clients, which is static, does not change and determines how active ingredients are absorbed and metabolized; this is very important for the effectiveness and for possible side-effects
- The current immune response from our Premium clients, which refers to the immune status that we have established in the course of our Covid-19 Immunization Program; this determines whether vaccination would be counterproductive

and thus inhibit the individual's own immune response or whether it would indeed be complementary

- The Covid-19 Risk Factor from our clients, determined by our in-house AI program SAIP, indicates how high the individual's need is for vaccination
- The Cytokine Storm Risk Factor from our clients, also determined by our Covid-19 Immunization Program and SAIP, shows us whether a vaccination could trigger a possible cytokine storm and thus weaken the immune system, thereby opening up the way for the SARS-CoV-2 virus
- In our Premium program, we always measure the T helper cells, T memory cells and the NK cells, at the moment even several times a year. The condition of the T helper cells and T memory cells, which also indicates whether there is any prospective benefit from a vaccination at all, and the condition of the NK cells, the production of which might be inhibited by vaccination, thereby weakening the immune system

As part of our Covid-19 Immunization Program, we have developed our own tool, namely the C-19 Vaccine and Medication Advisor, which enables us to review the drugs and vaccines that will be approved in a larger number in the future and to advise on whether these could be of benefit to the individual client based on his or her personal situation and health status. Our aim is to determine whether a vaccine can be used preventively or even complementarily to the natural immunization achieved by means of our Covid-19 Immunization Program and whether medications such as remdesivir and dexamethasone that have proved effective against infection can be taken without producing undesirable side-effects.

There are already samples of as yet unapproved vaccines circulating on the black market, and we therefore wish to protect our clients and give professional advice on which options make sense for which individual. Please do not self-administer any of these drugs!

Influenza vaccination 2020

In principle, we consider an influenza vaccination to be very useful, because a simultaneous infection with influenza and SARS-CoV-2 could cause severe complications. We are currently investigating this issue in consultation with the WHO.

As we have mentioned several times before, there is the problem that the number of samples forthcoming from the southern hemisphere was only 10% of number collected in previous years. These are essential for the preparation of a vaccine to be used next winter in the northern hemisphere. The starting point for developing an effective vaccine is therefore far less propitious than in previous years. We are monitoring developments very closely and will wait and see what the vaccine combination looks like before making any individual recommendations on vaccination. The reason why we are taking this matter so seriously is because the various vaccine commissions have developed very different vaccine combinations in recent years. Influenza is caused by different strains of the influenza virus, more precisely influenza A and influenza B virus strains. For a long time, there were two influenza A strains and one influenza B, i.e. three types of influenza pathogen. However, in the mid-1980s, a new, fourth strain emerged in addition to the three annual influenza virus strains: the influenza B strain split into two lines. Until the year 2000, these alternated from season to season, but since the turn of the millennium, both B strains have been circulating worldwide, which has led to an increasing burden of disease. Since the 2017/18 season, the German health authorities have been administering only quadruple flu vaccinations, i.e. formulated to combat all four influenza virus strains. This has been significantly more successful in recent years than the triple influenza vaccination which is administered in the USA for reasons of cost and is directed against both influenza A strains but only against one influenza B strain. This is also the reason why influenza has been more prevalent on the American East Coast than in Central Europe.

Furthermore, an influenza vaccination can potentially trigger a cytokine storm. This depends on the cytokine receptor families involved. We are testing these as part of our Covid-19 Immunization Program so that we can make a definitive recommendation for or against a vaccination.

Due to the obvious urgency of this topic, we will send current and individual recommendations directly to our members via our new app. We therefore strongly recommend that all our members download our (soon to be available) app so that these messages can be received directly. We will let you know when the app is available for download.

SALVAGENE HQ
Université Paris Sorbonne
125 Rue Saint-Jacques, 75005 Paris

SALVAGENE UK
52 Grosvenor Gardens • SW1W 0AU London UF
Tel: 0044 20 3287 0644

SALVAGENE USA
101 Avenue of the Americas, 8th floor • 10013 New York
Tel: +1 646 583 0370

info@salvagene.com • www.salvagene.com