Salvagene GROUP

Business Unit: SARS-CoV-2 Task Force
Keynote: #53

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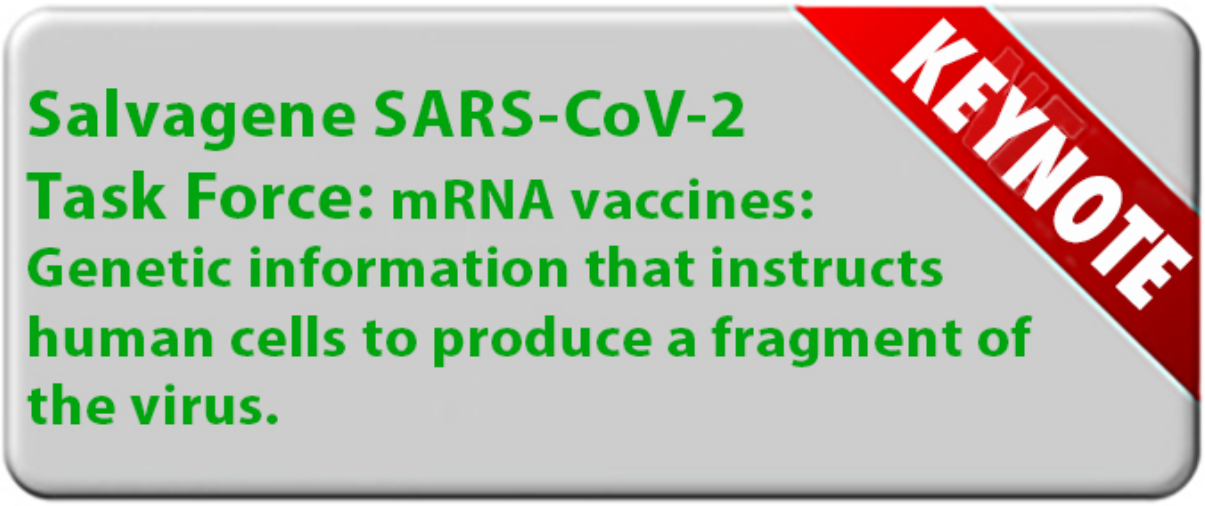

Dear Premium Customers,

Despite the fact that research in the field of mRNA has been going on for 30 years now, not a single medication based on this technology had succeeded in getting past the approval stage until the EMA authorized its use a few days ago.

In an unprecedented endeavor, BioNTech and its manufacturing partner Pfizer developed a vaccine in just ten months. The so-called "messenger RNA" is a single-stranded ribonucleic acid. It functions as a transcript of a section of DNA that forms part of a gene. This contains genetic information for the construction of a protein within a cell. It is an absolutely natural substance that is not stable and is degraded immediately. This information causes the human cell to produce a fragment of virus, thereby triggering an immune response that is already present if and when an actual infection occurs. The virus is thus unable to spread, and the disease itself is unable to take hold.

And as we have reported on previous occasions, it is a technology that has been proved to work well. We can also completely rule out any suspicion that it might interfere directly with the human genome itself. However, our core competence at Salvagene lies in epigenetics, and we know from our experience that basically all environmental influences can lead to epigenetic changes. These may be either positive or negative in nature, and it is not possible to predict with any certainty what kind of epigenetic change might be triggered by an mRNA-based vaccine. Potential long-term consequences cannot therefore be completely discounted.

What we can say with certainty is that mRNA-based vaccines are safer than, for example, the Pandemrix vaccine administered in 2009, which was developed in a fast-track procedure and administered to around 30 million people in response to the flu virus of that year. Months after the vaccination campaign, it emerged that the formulation had caused narcolepsy in at least 1,300 people, mostly children and adolescents. A full explanation of what happened was not forthcoming until 2015 when it turned out that the vaccine had triggered an autoimmune reaction directed against a hormone receptor which plays a role in the wake-sleep rhythm.

On the other hand, there is one specific genome – namely that of the SARS CoV-2 virus itself – that mutates even more strongly than predicted, as we have already explained in previous Keynotes. According to our sources, an official statement will be issued in the next few days that the BioNTech vaccine is effective against the B.1.1.7 variant, although a marginal reduction in efficacy cannot be completely excluded. As soon as we have an announcement to this effect, we will be giving the all-clear to Premium clients whose recommendation status had been set to “Hold”.

The situation is different with the 501.V2 variant. We suspect that it is far more transmissible than the B.1.1.7. variant and significantly more dangerous, as it has an increased propensity to

infect younger individuals in otherwise good health. We are currently in contact with the sequencing centers in London and Johannesburg where research is taking place into this variant. As soon as reliable information is available, we will report back to you.

We currently have no information on the tolerability and efficacy of the AstraZeneca vaccine against these mutations. Patients in the UK began receiving the jab on Monday 4th January. Because of the much easier handling, we expect the rollout in the UK will be successful, especially with the strong centralized organization of the NHS. In the absence of any statement from AstraZeneca about effectiveness against the 501.V2 and B.1.1.7. variants, we are still reserving our judgment on their vaccine.

The same also goes for Moderna who have not issued any definitive statement on either variant. We have had some reports of cases where severe side-effects were registered. For example, from a doctor in Mexico who was the first to diagnose encephalomyelitis, an inflammation of the brain and spinal cord.

We will continue to make specific recommendations regarding vaccination in the coming days and weeks based on the local situation in each country and the individual health status of our clients.

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