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PIETER
CULLIS



PhD

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PROFESSOR, DEPARTMENT OF BIOCHEMISTRY
AND MOLECULAR BIOLOGY, UNIVERSITY OF
BRITISH COLUMBIA

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For their pioneering work developing nucleoside-modified mRNA and lipid nanoparticle (LNP) drug delivery: the foundational technologies for the highly

BioNTech-Pfizer Exhibit 1113
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Drs. **Karikó** and **Weissman** discovered how to engineer mRNA – a molecule that carries instructions for making proteins – so that it could be used to produce the desired protein after introduction into mammalian cells. They overcame the inflammatory activation and rapid degradation of mRNA by modifying the RNA so that it could resist quick breakdown and avoid activating RNA sensors. Despite skepticism from others, Drs. Karikó and Weissman saw the potential of RNA therapeutics for vaccines and other applications and the data kept leading them forward. However, one major challenge remained: how to introduce the mRNA into the body in a way that it would be protected from degradation, and could enter into the cells for protein production.

Dr. Cullis had been working with such packaging systems for the past 50 years. Dr. Cullis is a pioneer in lipid chemistry and the formation of lipid nanoparticles (LNP). From his foundational work, many different clinical applications of LNPs have been developed, such as delivering anticancer drugs to cancer tissues while limiting toxicity in normal tissues. In the case of mRNA the LNP are designed to form a protective bubble around the mRNA and enable delivery to the interior of target cells. The LNP technology is critical to the potency of mRNA vaccines.

Following the emergence of the SARS-CoV2 virus, various teams around the world began working on potential vaccines using the knowledge gained about the mRNA and lipid nanoparticle through decades. The idea for both the Pfizer/BioNTech and Moderna vaccines was to introduce modified mRNA molecules into the body via LNPs to briefly instruct human cells to produce the coronavirus' spike protein. The LNP-activated immune system would recognize the encoded viral protein and develop antibodies and immune memory so that the immune system would attack the coronavirus when entering the body.

THE IMPACT:

The work of Drs. Karikó, Weissman and Cullis enabled the rapid availability of highly effective and safe COVID-19 mRNA vaccines, which has become an important tool for the control of COVID-19 pandemic. Importantly their pivotal discoveries also have the potential to revolutionize the future delivery of effective and safe vaccines, therapeutics and gene therapies. The success of the mRNA vaccines for COVID-19 suggests paths forward for similar vaccines for viral threats like influenza or HIV. Clinical trials are already underway to test mRNA vaccines to prevent diseases, caused by Zika virus, chikungunya and rabies infections.

The COVID-19 mRNA vaccines developed by Pfizer/BioNTech and Moderna are built on over 30 years of established scientific research and highlight the importance of basic and applied research, and international collaboration.

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