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CiFlu®: Development of a novel subunit influenza vaccine candidate based on the ciliate performance expression system

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The critical annual manufacturing process for seasonal influenza vaccine based on embryonated chicken eggs, involves numerous steps and takes on average 6 to 8 months to complete. This often means that vaccine is only available late into the flu season. The timely availability of an effective influenza vaccine, at or before the flu season starts, is even more acute for vulnerable highest risk groups such as persons 65 years of age and older. The lack of timely availability of seasonal/pandemic vaccine has raised significant questions about the utility of the current, antiquated, cumbersome, expensive and unsafe manufacturing platform involving chicken eggs. Safety concerns about cell culture based virus proliferation processes called also alternative flu vaccines production processes into question. Now new recombinant antigen manufacturing platforms were postulated to reduce production time and costs. Cilian's flu vaccine CiFlu® is a cost-effective subunit vaccine based on the heterologous expression of recombinant Influenza hemagglutinin (rHA) in the ciliate *Tetrahymena*. Utilizing its CIPEX-System as such a manufacturing platform, Cilian has successfully demonstrated repeated expression of rHA at high yield: Four subunit vaccines has been expressed and shown to be functionally active. Mice were first immunized with the monovalent rHA. HA antibodies were harvested and its ability to inhibit the respective influenza strain was tested. The results demonstrated comparable or better efficacy (in vivo inhibitory immunogenicity) to monovalent vaccine from chicken eggs. Cilian meanwhile received a positive scientific advice from the German Paul Ehrlich Institute for CiFlu® and is developing a comprehensive clinical plan.

Biography

Marcus Hartmann has spent his scientific career investigating protozoan organisms, particularly Ciliates. He has worked for the Central Research Department of Aventis, Frankfurt, Germany and was a Post doctorate in an academic working group at the University of Munster. His Postdoctoral study dealt with research in the field of commercial applications of protozoan organisms. Based on his extensive scientific experience in the field Ciliate biotechnology, he founded Cilian and since then he has headed the Company's R&D team. He is the author of numerous scientific publications, recitations and patents in the area of Ciliate biotechnology. One of the main breakthrough of his team was the first-ever production of therapeutically usable proteins in Ciliates.

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