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SupraAntigen™ technology platform; Manufacturing and development of vaccines for the treatment of Alzheimer disease

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Abstract

Alzheimer's disease (AD), the most common form of dementia, is characterized by pathological Amyloid beta (Aβ) deposition into plaques and neurofibrillary tangles due to aggregation of hyperphosphorylated Tau protein in the brain. The benchmark for AD vaccines targeting Aβ, is the generation of antibodies without the introduction of antigen specific T-cells, which have been reported to cross the blood-brain-barrier and cause encephalitis in 6% of AD patients receiving anti-Aβ vaccine. We developed a liposome vaccine platform technology that combines (i) antigens lacking T-cell epitopes, (ii) adjuvant signaling via TLR stimulation and (iii) B-cell receptor cross-linking by repetitive assembly of epitopes. AC Immune has developed its own vaccine manufacturing technology in order to make it easily up-scalable and compatible with cGMP principals. Our present work highlights AC Immune's development approach for bringing a AD vaccine under clinical environment. The rationale for process development was to simplify the process, improve the homogeneity of the liposomes, reduce manufacturing time and make it easier to scale the process. Our data indicates that AC Immune's manufacturing strategy is suitable for the preparation of Drug Product for preclinical and clinical studies at 100 – 1,000 mL scale. The following additional comments can be made.

(i) The preparation of the liposomes appears flexible and robust, and should be readily scalable.

(ii) It is likely that the quality of the peptide raw material, and perhaps its tendency to aggregate may have an impact on the level of protein incorporation into the vesicles, the homogeneity of the liposomes and presence of aggregates. The level of peptide incorporation into the liposomes was generally quite high and the level of unincorporated peptide was low.

(iii) The current manufacturing strategy appears suitable for preparation of intermediate (100 – 1,000 mL) batches; however, large scale batches may use an in-line mixing system to mix the protein with the vesicles. Studies to optimize the detergent to protein ratio, detergent to lipid ratio, and lipid concentration at the time of peptide reconstitution may also be required at this time.

Clarifying filtration provides a useful strategy to improve the sterile filtration process, and remove some of the aggregates and/or larger particles that are present in the formulation.

Biography

Pedro Reis did a PhD on Biophysics in 2008 at Chalmers University of Technology, Sweden. Afterwards, he was appointed as Primer Researcher at Baylor College of Medicine, Houston and at UNIL's Biochemistry Department, Switzerland. Since August 2009, Pedro Reis has been working as a Project Leader of Vaccine Manufacturing at AC Immune SA, which is a Swiss-based biopharmaceutical company and a leader in Alzheimer's Disease drug development. AC Immune SA has been developing innovative therapeutics with "best in class" potential against Alzheimer's disease and other conformational diseases along three axes: vaccines, antibodies and small molecules.