Adenovirus Vectors meet critical FDA requirement regarding risk of contamination with infectious agents; a critical hurdle on their way to clinical studies can be overcome

SIRION Biotech has its viral vectors tested by SGS Vitrology for replication competent adenovirus (RCA)

Munich, **12 June 2014**, viral vectors present themselves as a new class of biologics that help treat diseases caused by defective genes / proteins ("gene therapy"). About 20 companies worldwide the majority of which originating in the United States are applying viral vectors to conduct clinical studies.

A key safety concern is the risk of transmission of infectious agents by inadequately tested products, specifically any replication competent adenovirus (RCA) still being administered to the patient. RCA comes from working with the most common production cell line used for replication defective adenovirus vectors, HEK293. Besides ethical concerns around HEK293, the cell line may complement the critical E1 replication gene that is lacking in the vector. The concern that RCA could lead to adverse events in patients led FDA to recommend limits on RCA levels in clinical lots of adenovirus vectors.

SIRION Biotech engineered adenovirus vectors with CAP®-cells that are being derived from normal human amniocytes and which yield authentic human glycosylation patterns. Large scale production processes were mimicked. SGS, the world's leading inspection, verification, testing and certification company, applied an extended in vitro assay using A549 cells. Following an initial cytotoxicity assay, the vector preparation was tested in an interference assay at various titres. Cultures were incubated for 31 days with 3 blind passgaes at 7 day intervals. No evidence for the presence of RCA was found, no interference with the wild type Ad5 control in the presence of the test material.

About SIRION Biotech www.SIRION-Biotech.com

SIRION Biotech started in Munich in 2007 with the idea of enabling novel cell models closer to reality than ever before. This required the assembly of an all-encompassing, novel viral vector platform. Both, designing de novo viral vectors and the subsequent creation of custom cell models will pave the way for superior compound development in the life sciences. Many of SIRION's viral vectors are being used to conducting clinical studies. SIRION's technologies have been validated in over 300 single projects with more than 100 academic and industrial partners.

As a result, cell models for drug discovery and development have become highly reliable, as have the use of new viral vectors in gene therapy and vaccine studies.

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