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CASE STUDY

VALIDATION AND TRANSFER OF BIODISTRIBUTION AND VIRAL SHEDDING ASSAYS IN DEVELOPMENT OF AN ONCOLYTIC VIRUS IMMUNOTHERAPY CANDIDATE

INTRODUCTION / OVERVIEW

Immunotherapy in cancer is rapidly evolving and increasingly investigated for both its potential across a range of tumor types, and its synergistic activity when combined with other treatment modalities. Oncolytic viruses in particular represent a promising new immunotherapeutic approach that offers the potential to deliver customized therapy to specific targets, at the cellular level. Oncolytic viruses are replicating therapeutics that selectively infect and replicate within tumor cells, without harming normal tissues. In the development of this new class of drugs that combine selective tumor cell killing and induction of anti-cancer immune reactions, two of the most significant safety and efficacy concerns are rapid neutralization and clearance of virus particles.

SITUATION / CHALLENGE

As part of phase II, multicenter, clinical trial; a large pharmaceutical company, with a promising new oncolytic virus immunotherapy candidate, partnered with Eurofins Viracor BioPharma to investigate DNA biodistribution, viral shedding, and potential transmission during and after treatment in subjects with advanced-stage cancer. NAb, with a qPCR assay, added later as an endpoint.

SOLUTIONS

For both primary and secondary outcome measures of the study, Eurofins Viracor optimized and validated a quantitative polymerase chain reaction (qPCR) assay for use on multiple specimen types (injection site, oral mucosa and viral lesion swabs, urine, and whole blood) and a reflex TCID50 assay for use on swab specimens determined to be positive by qPCR.

qPCR Assay

Samples were tested for viral DNA using a validated virus-specific qPCR–based assay (no detection of non-target nucleic acids, including two wild-type virus strains).

TCID50 Assay (50% tissue culture infectious dose)

If the result of the qPCR testing was positive, then a 50% tissue culture infective dose (TCID50) assay was performed on the swab sample to measure viral infectivity. The qPCR-positive swab samples were tested for the infectious virus in the validated TCID50 assay, which quantifies the amount of sample required to produce a cytopathic effect in 50% of inoculated tissue culture monolayers.

Viral TCID50 Value and Virus Copy Number Correlation

In an additional study, the sponsor asked Eurofins Viracor to perform linear regression analysis on the log10 values generated by the virus TCID50 and Real-Time PCR testing to determine the correlation between TCID50/mL values and oncolytic virus copy numbers by the respective assays. This study was intended to result in an improved characterization of the relationship between the two assay results under ideal conditions to assist in the interpretation of clinical study data. (viral DNA copies/mL vs viral DNA copies/µg).

CASE STUDY

Validation and Transfer of Biodistribution and Viral Shedding Assays in Development of an Oncolytic Virus Immunotherapy Candidate

OUTCOME

- Eurofins Viracor's in-depth investigation of the biodistribution, shedding, and transmissibility of virus in the target population confirmed observations from previous clinical trials that the oncolytic virus is unlikely to be transmitted from treated patients to their close contacts.
- The additional correlation study provided an improved characterization of the relationship between the two assay results under ideal conditions, assisting in the interpretation of clinical study data.
- The study provided additional data on the efficacy and safety of the oncolytic virus in patients with advanced-stage cancer.

In this clinical trial, Eurofins Viracor performed an extensive study characterizing the biodistribution and transmissibility of an intratumoral oncolytic virus. As such, the methodological approach and results of the study may be of value in the development of future oncolytic viruses for the treatment of certain cancers.

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