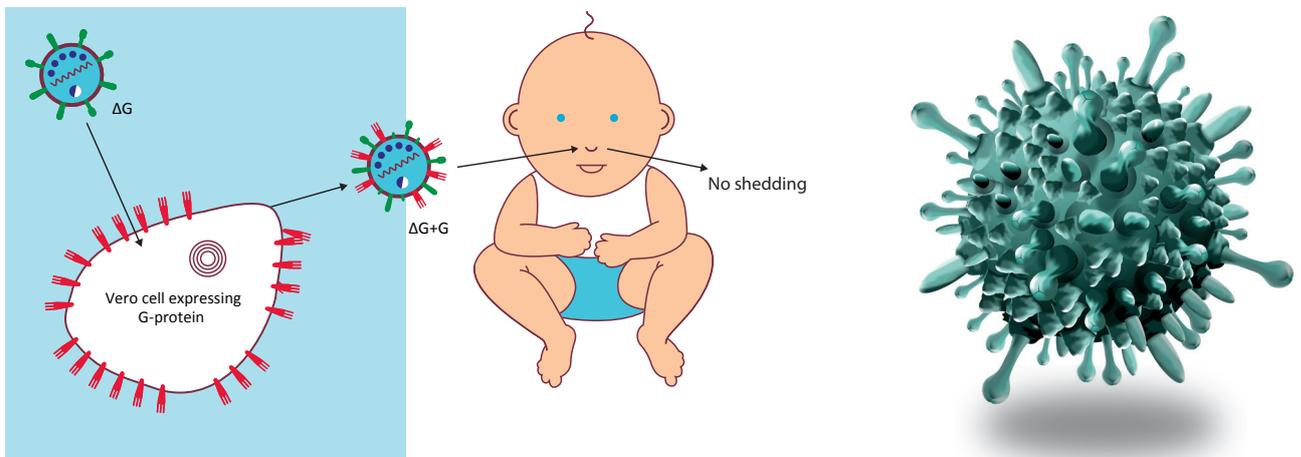




## Vaccine concept based on a live Respiratory Syncytial Virus with a genomic deficiency complemented in trans



### Introduction

Since the discovery of Respiratory Syncytial Virus (RSV) attempts to produce a safe and effective inactivated vaccine have failed. Our opinion for a viable approach is a live RSV vaccine.

### Intravacc technology

- A RSV virus with genomic deficiency for G protein was constructed using reverse genetic and rescue techniques.
- Complementation of this  $\Delta G$  virus by growing it on a Vero cell line expressing the viral G protein resulted in a  $\Delta G+G$  virus.
- Since this virus carries the G protein but has no genetic coding for G, it is attenuated upon administration. Consequently, it is not able to produce infectious progeny.

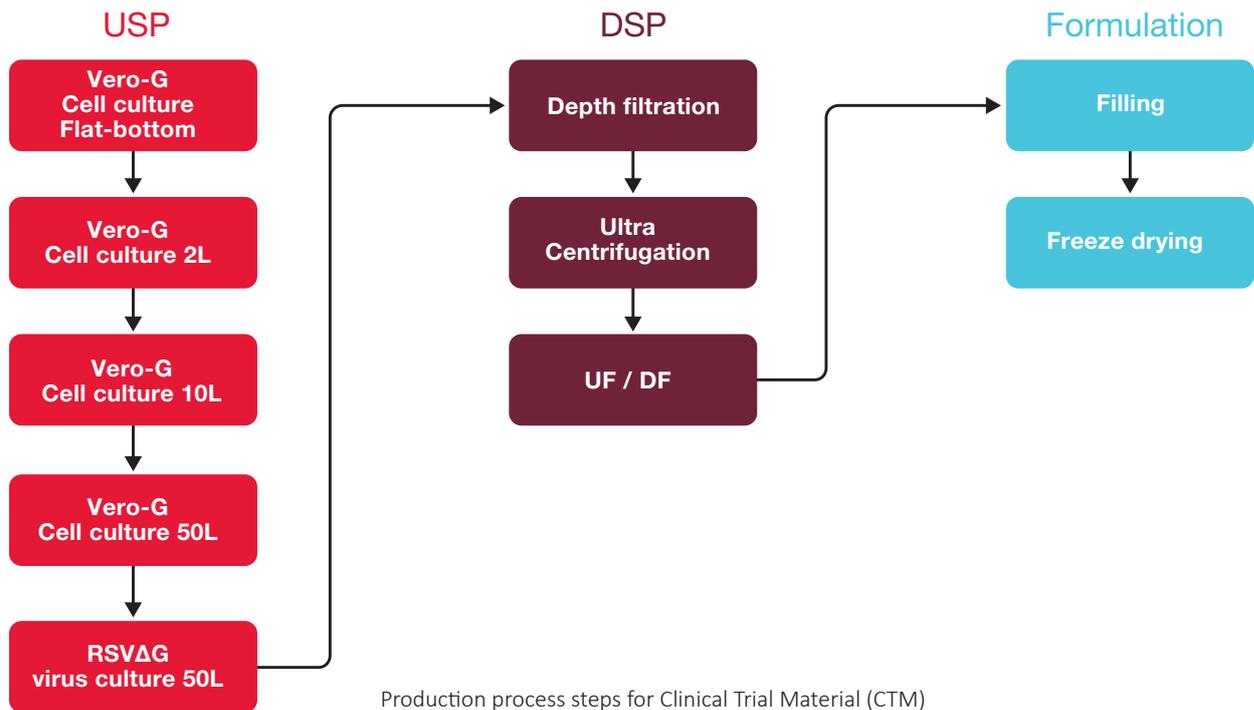
### Technology status

Full sequences of the  $\Delta G$  RSV virus and G insert in vero celline are available. A target production process is available based on adherent Vero cell growth. The vaccines are lyophilized and after reconstitution delivered intranasally. A QC test panel has been developed for testing and release of clinical material for phase 1 and 2 clinical trials and an extensive stability program exists for the vaccine bulk materials and final lots.

### Proven Safety and Effectiveness

A large set of cotton-rat data has been produced and is available. It shows that the obtained virus strains are attenuated and safe. There is no immune-enhanced disease in the animal model. The vaccines are immunogenic and protect against challenge with high doses of wildtype RSV in a dose-dependent manner. Multiple doses give longer-lasting protection. Protection is subtype independent.

Neonatal cotton rats that are vaccinated with our conceptual vaccines directly after birth, are protected also in the presence of maternal antibodies.



## Clinical Program Designed

A draft clinical program for the target group (newborns) has been designed with advice from pediatric professionals and is part of the licensure package.

## Competitive advantage of Intravacc technology

Licensed vaccines against RSV are still not available. Intravacc RSV vaccine development is in an excellent position to become a prime candidate for pediatric RSV vaccine programs.

## Partnering Opportunity

Intravacc offers a technology for a live attenuated recombinant RSV vaccine, to be administered intranasally in newborns, which is the primary target population, as well as the elderly. The technology and associated intellectual property rights are offered for partnering via a license. The Intravacc IP comprises the complemented  $\Delta G+G$  virus as well as  $\Delta G$  RSV virus. Intravacc IP is based on patent application WO 2005061698, including 14 family members, as well as IP in the filing phase.

## Intravacc's R&D program includes:

- Prophylactic and therapeutic vaccine development
- Development of animal component free production processes and analytical methods
- Adjuvant technology and alternative delivery systems
- Contract based process development and consultancy on production and purification
- Conjugation of carbohydrate based vaccines.

## Intravacc

The Institute for Translational Vaccinology is an experienced, not-for-profit R&D organization. With our unique capabilities and infrastructure, we are able to optimize vaccines, vaccine processes and vaccine technologies. Our aim is to increase equality in access to vaccines throughout the world in order to contribute to public health. We achieve this by transferring our knowledge and technologies to public and private partners worldwide and collaborative R&D. A team of 150 professionals is at your disposal at Science Park Bilthoven in The Netherlands.

## Contact

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