GERMAN CANCER RESEARCH CENTER
IN THE HELMHOLTZ ASSOCIATION

Research for a Life without Cancer

TECHNOLOGY OFFERS

Dry Pharmaceutical Composition For Inhalation (P-1406)

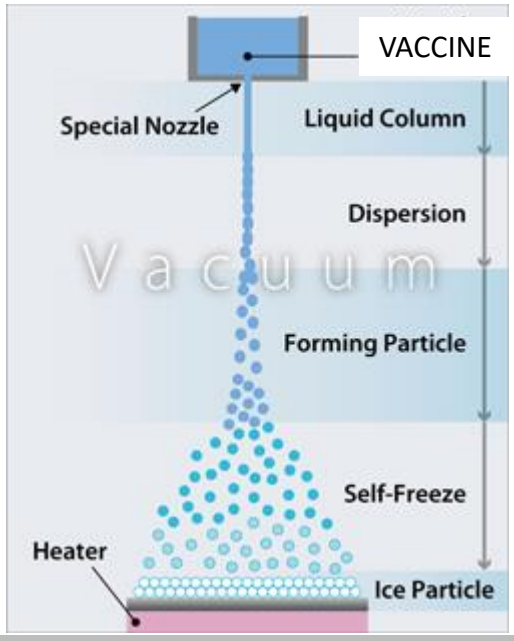
Dry-powder formulation of a thermostable antigen for vaccine delivery to the lungs

EXECUTIVE SUMMARY

Vaccine administration is usually performed via intramuscular or subcutaneous injection. However, there are few challenges associated with this mode of delivery, such as a poor physico-chemical stability of the vaccine solution, which requires transportation and storage under temperature controlled conditions. This significantly increases vaccine (and health) cost as it dramatically limits vaccine availability, especially in developing countries. A dry- powder vaccine formulation is thermostable and easy to transport.

Vaccine administration by injection can be painful, it may generate adverse psychosomatic effects (so called 'lipothymic reaction') and it must be performed by trained healthcare personnel.

A dry-powder vaccine, instead, can be filled into monodose capsules and administered via ready-to-use inhalers. The technology uses a new formulation for the manufacturing of a respirable, dry-powder vaccine (i.e., containing both a recombinant antigen and an immune-stimulant) suitable for pulmonary administration. In addition to a greatly facilitated (i.e., unassisted) administration, this mode of delivery enhances immunogenicity and ultimately the efficacy of vaccination.



Caption / Copyright

Category	Indication	Development stage	Seeking
Method	Infectious Diseases	Preclinical	Licensing, Development Partner

BENEFITS

- No specific storage, transport/ distribution temperature requirement.
- Single-phase, ready to use and easy to administer composition, suitable for needle-free, pulmonary delivery, not requiring any specialized healthcare personnel.
- Compatible with a variety of manual inhalers
- For special applications or alternative treatments, the powder can be dissolved and used to generate a ready-to-inject solution.

TECHNOLOGY BACKGROUND

A distinctive aspect of the invention is a pharmaceutical dry-powder formulation composed of particles, with a median aerodynamic diameter of approximately 3 µm, containing the antigen along with a bulking agent and an amphiphilic immune–adjuvant acting as both a biologically active component potentiating the immune response, and as a technological excipient that improves powder flowability and respirability. The particles are generated by spray-drying a solution containing a thermostable recombinant antigen, a bulking agent and an amphiphilic adjuvant. During the spray-drying process the solution is nebulized in the form of small droplets, so that evaporation of the solvent during the drying-phase yields adjuvant-coated particles with the protein antigen embedded in the bulking agent inside the particles. The immune-adjuvant is a biologically active (TLR-4 agonist) detoxified derivative of the lipopolysaccharide constituent of gram-negative bacterial cell walls; similarly amphiphilic immune-stimulant compounds can be incorporated within the dry-powder formulation. The resulting powder, which is fully stable up to a temperature of at least 37°C, can be aliquoted into single dose units in the form of hard capsules, and administered to a patient by a suitable dry-powder inhaler.

DEVELOPMENT STAGE

Several tests were successfully performed to evaluate the immunogenicity and lung deliverability of the dry-powder vaccine by intra-tracheal administration to mice.

APPLICATIONS

Easy to use respirable vaccine powder with unique composition properties for prevention of suitable for infectious disease prevention/prophylaxis. Dissolution of the powder inside the lungs enhances immunogenicity and overall potency of vaccination.

INTELLECTUAL PROPERTY

Patent application was filed as EP18201253.4: “Dry Pharmaceutical Composition for Inhalation” on October 18, 2019

PUBLICATIONS & REFERENCES

- “A drug powder formulation for inhalation administration and a process thereof” patent publication by Francesca Buttini, Paolo Colombo & Chiara Parlati EP2313114
- ‘‘Particles for use in pharmaceutical composition’’ patent publication by David Alexander Vodden Morton & John Nicholas Staniforth EP1337239B1.

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ABOUT THE DKFZ INNOVATION MANAGEMENT

Working at the interface of research and industry, the Innovation Management of the German Cancer Research Center (DKFZ) helps to get new cancer medications, diagnostic tests, and research instruments onto the market as quickly as possible.

The DKFZ with its more than 3,000 employees is the largest biomedical research institution in Germany. At the Center more than 1,300 scientists investigate how cancer develops, identify cancer risk factors and endeavor to find new strategies to prevent people from getting cancer. They develop novel approaches to make tumor diagnosis more precise and treatment of cancer patients more successful. DKFZ is a member of the Helmholtz Association of National Research Centers, with ninety percent of its funding coming from the German Federal Ministry of Education and Research and the remaining ten percent from the State of Baden-Württemberg