

Taking a multidisciplinary approach to allergy and immunology

Inmunotek brings a range of skills and specialties together to create vaccine-based approaches for the treatment of allergy, recurrent infections and other immune-related diseases.

Based in Madrid, Inmunotek's focus is on the development, manufacture and marketing of products in the field of allergy and immunology. Inmunotek's marketed product portfolio includes immunotherapies, diagnostics and medical devices.

While the company is based in Spain, Inmunotek has sales offices and subsidiaries in Portugal and in the Spanish-speaking countries of Latin America, and has distribution and contract manufacturing partnerships around the world.

The company has had a sustained revenue growth rate of around 20% over the past 10 years and was in the Financial Times' top 1000 of Europe's fastest growing companies in 2017. The company's R&D program includes allergy vaccines, mucosal vaccines to prevent infections, vaccine adjuvants and antitumor vaccines.

Building a new concept in vaccines

Vaccines in development at Inmunotek include a pipeline of polybacterial whole-cell vaccines. These target the mucosal innate immune system and aim to trigger a broad anti-infective response.

"We are very excited about our development of a pipeline of bacterial vaccines for active mucosal immunotherapy to prevent recurrent infectious diseases in adults and children," said Miguel Casanovas, medical director at Inmunotek. "We describe these as 'trained immunity' vaccines," said Casanovas, "and we think the concept could be used to create a platform with potential against a wide range of infections."

Vaccines usually depend on adaptive immunity, with the induction of T and B memory cells that are triggered the following time the pathogen is encountered. The innate immune system can also 'remember' pathogens, in what has been described as 'trained immunity' (**Fig. 1**). This supports the development of longer-lasting immunity against both vaccine-related and unrelated bystander pathogens.

Inmunotek's mucosal vaccine pipeline

Inmunotek's bacterial vaccines use the 'trained immunity'effect, and are made up of mixtures of inactivated whole-cell bacteria that are administered under the tongue. MV130 (Bactek) is in development to prevent recurrent respiratory tract infections, and MV140 (Uromune) targets recurrent urinary tract infections.

One of the advantages of using mucosal rather than parenteral vaccines for infections in the respiratory and urinary tract is that they stimulate the mucosal immune system, which is the primary first defense against these types of infection.

"In preclinical studies, MV130 and MV140 show a broad activity against both related and unrelated

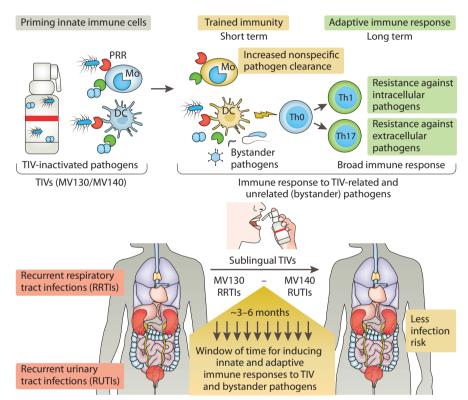


Fig. 1 | Trained immunity-based vaccines. DC, dendritic cells; Mo, monocytes; PRR, pattern recognition receptors; Th, T helper cell; Th0, naïve T cells; TIV, trained immunity vaccine.

antigens, triggering immune responses to pathogens not in the bacterial vaccine preparation as well," said Casanovas.

MV130 has completed a phase 3, double-blind, placebo-controlled clinical trial for the prevention of recurrent wheezing in children, a condition mainly caused by viral infections, such as rhinoviruses. There are no specific vaccines currently available for these viral infections.

"The recurrent wheezing study showed outstanding positive results," said Casanovas.

The same vaccine is currently in a double-blind, placebo-controlled phase 3 efficacy and safety study in patients with chronic obstructive pulmonary disease (COPD), with an aim to reduce the number of COPD exacerbations. This study is due to be completed in 2019.

Also due to be completed in 2019, MV140 is in a double-blind, placebo-controlled phase 3 safety and efficacy study to assess its ability to reduce the recurrence of cystitis.

"Cystitis can be caused by uropathogenic bacteria and requires long periods of treatment with antibiotics. Pilot studies with MV140 have shown that this preparation prevents recurrence of infection with bacteria, including those not in the vaccine, showing a protective effect that goes beyond the bacterial composition of MV140," said Casanovas.

Inmunotek believes that broadly active vaccines that target trained immunity may be a valuable alternative when conventional vaccines are not available or when a number of different microorganisms cause co-infections.

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