

## **CIMAvaxEGF, an Epidermal Growth Factor (EGF) based cancer vaccine for non small cell lung cancer therapy: Product development and post-marketing experiences**

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The system composed by the EGF and its receptor (EGFR) has become in the last years an important target for cancer treatment. Different Monoclonal Antibodies targeting the EGFR as well as molecules tyrosine kinase inhibitors are currently in the clinical practice.

Our approach consists in an active immunotherapy, a cancer vaccine devoted to create an immune response as specific antibodies against the EGF. The proposed mechanism of action of this vaccine is that the specific antibodies bind the circulating EGF avoiding it further binding to the EGFR and then, the initiation of the proliferation mechanisms derived from this binding. This product development began in 1992, with all the preclinical testing including toxicology. The clinical experience with the EGF based vaccine began in 1995. From then up to now, 6 proof of principle (Phase I-II) clinical trials demonstrated the immunogenicity, safety and preliminary evidences of effect in survival of vaccine, as well as allowed to select the product formulation for going to further Efficacy Trials. Two Efficacy trials (randomized Phases II and III) demonstrated that vaccination provokes an increase in survival of vaccinated patients as compared with non-vaccinated randomized controls, giving the proof of the vaccine efficacy. This vaccine received Regulatory Registration in Cuba and Peru, and is in process of Registration in Brazil, Colombia, Argentina, Paraguay and in Phase III trials in Europe.

Experiences with long term vaccination demonstrate the feasibility of using this vaccine as a chronic vaccination, what gives a tool for the treatment of advanced cancer as a chronic disease, could be maybe not cured, but controlled, giving to the patients long periods of survival with good quality of life.

### **Biography**

Dr Gisela Gonzalez Marinello has completed her Ph.D in 1998 at the Havana University. She is Senior Researcher at the Center of Molecular Immunology in Havana, Cuba with huge expertise in Immunotherapy, specifically in the discovery and development of Cancer Vaccines. She has been Global Project Leader of the vaccine CIMA vax EGF during all its stages of development. Have more than 30 papers in peer reviewed journals.

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