

A new Lyme disease vaccine – bravery to be rewarded

LONDON, UK----18st August 2018----ExpertREACT. This month VacZine Analytics, a UK-based strategic research publisher exclusively focused on vaccines and infectious diseases, releases a brand-new commercial assessment of Lyme Borreliosis (Lyme Disease) vaccines.

Lyme Borreliosis (LB) or Lyme disease is an inflammatory disorder caused by infection with the bacterial spirochete *Borrelia* genospecies. The pathogen is transmitted to humans through the bite of infected *Ixodes* tick species which feed upon reservoir hosts such as mice and other small vertebrates. LB, which is endemic in large areas of Europe and North America, can cause a wide range of disease symptoms which range from a mild treatable rash (erythema migrans, EM) to serious multistage complications of the neurological (neuroborreliosis) and musculoskeletal systems.

Aside from increased awareness and testing, experts believe the incidence of LB is increasing partly due to expanding vector populations. There are an estimated 300,000 estimated cases of Lyme disease annually each in the US (CDC figures) and EU*. The disease is significantly underreported and has high profile chronic implications for many individuals. Only recently, the US government has set up a Federal Advisory Committee (Tick-Borne Diseases Working Group) through the 21st Century Cures Act, Section 2062 to address what some consider a public health crisis. However, funding to tackle LB, compared to other diseases such as Hepatitis C, influenza and HIV/AIDS is low <\$50m in 2017, despite significant public pressure.

GSK Biologicals FDA-licensed an OspA-based recombinant Lyme disease vaccine, **LYMERix** in 1998 which, despite demonstrating good efficacy, was later withdrawn mainly due to the spread of disinformation regarding its safety profile. Both **Baxter Vaccines** and **Sanofi Pasteur** were also developing OspA-based approaches, but development was presumably halted due to a perceived lack of demand. Presently, **Valneva** (France) appears to have the only human Lyme disease vaccine in development (**VLA15**), a multivalent approach which has initiated Phase II studies. There are many drivers to developing a new Lyme disease vaccine, and the renewed Valneva effort is both brave and pioneering. The Lyme disease field faces many controversies and challenges. There's strong debate regarding surveillance, diagnosis and treatment but also with the strong backdrop of an aggressive US antivax movement, is a new discretionary vaccine welcome? The EU might be more receptive to a new vaccine, disease incidence is high but manifestations of LB are different than in the US. However, there's been good implementation of Tick-Borne Encephalitis (TBE) vaccines in certain countries, which may form a good awareness platform in the general public.

VacZine Analytics' latest **MarketVIEW** report is composed of a comprehensive Executive Summary presentation (~210 slides, .pdf) + MS Excel-based model which forecasts the potential commercial value of a putative Lyme Borreliosis vaccines across 27 major Western markets to 2040. Both adult and pediatric, as well as risk-persons, are considered with 3 pricing scenarios (LO, BASE and HI). A detailed review of disease background and epidemiology is included along with current treatment, unmet needs and rationale for vaccine approach with a review of the latest key working group viewpoints and controversies. **Vaccine Target Product Profiles (TPP)** are defined based on recent R&D understanding, along with commercial model assumptions per nation. This analysis is ideally suited to any organisation wishing to understand and justify new investment into this highly important opportunity.

For more information please visit our website or contact info@vaczine-analytics.com

About VacZine Analytics

VacZine Analytics is an established strategic research agency based in the United Kingdom. Its aim is to provide disease and commercial analysis for the vaccine industry and help build the case for developing new vaccines and biologics.

For more information please visit our website www.vaczine-analytics.com

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