Dynavax's HEPLISAV - a hepatitis B vaccine with a first-in-class adjuvant

Description: Dynavax's HEPLISAV is a hepatitis B (HBV) vaccine under FDA review for seroprotection of adults 18 to 70 years of age. A biologic license application in chronic kidney disease will come once the initial approval is secured. HEPLISAV contains the same antigen as currently marketed HBV vaccines. The novelty is the adjuvant: a Toll-like-receptor 9 (TLR9) agonist. This is a first-in-class adjuvant both in the US and Europe. The efficacy of HEPLISAV is unquestionable. It achieves greater, faster and more durable seroprotection as compared to GSK's Engerix-B. HEPLISAV's Achilles' heel is safety. FDA is ultra-conservative regarding adjuvants and there is very low tolerance to risk. To-date, all vaccines in the US, except for GSK's Cervarix contain alum as the adjuvant.

This report provides an in-depth discussion of HEPLISAV's risk/benefit, with a particular focus on the risk of autoimmunity, and its potential impact on the regulatory process and outcome using Cervarix as the role model for bringing a new adjuvant to the market. We provide revenue projections for various scenarios as well as their odds of success.

Contents:

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HEPLISAV

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SUMMARY OPINION

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