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ASIA EDITION

ECA approves HEPLISAV B®, a 2 dose adult Hepatitis B Adjuvanted Vaccine

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HEPLISAV B vaccine delivers higher levels of protection in just 1 month and is ready to be launched in Europe this year

Dynavax Technologies Corporation, a biopharmaceutical company focused on developing and commercializing novel vaccines, updated that the European Commission (EC) has granted Marketing Authorization for HEPLISAV B (Hepatitis B Vaccine (Recombinant), Adjuvanted) for the active immunization against hepatitis B virus infection (HBV) caused by all known subtypes of hepatitis B virus in adults 18 years of age and older. The approval was issued following the European Medicines Agency (EMA) Committee for Medicinal Products for Human Use (CHMP) positive opinion on the company's Marketing Authorization Application. The approval and CHMP recommendation were based on the positive benefit-risk for HEPLISAV B as demonstrated by the safety and immunogenicity results of three Phase 3 clinical trials.

Ryan Spencer, Chief Executive Officer of Dynavax said, "With a two-dose regimen that takes only one month to complete and a statistically significantly higher seroprotection rate in head-to-head clinical trials, HEPLISAV B provides a unique opportunity to address known challenges with compliance, while delivering higher levels of protection compared to the three-dose regimen of the comparator vaccine. We are pleased that HEPLISAV B has received this latest approval and look forward to its launch in Europe expected later this year."

European Commission marketing authorization approval is valid in all EU and EEA-European Free Trade Association (EFTA) states (Norway, Iceland and Liechtenstein). HEPLISAV-B is now approved in the U.S. and EU.

HEPLISAV-B® [Hepatitis B Vaccine (Recombinant), Adjuvanted]
HEPLISAV-B is an adult hepatitis B vaccine that combines hepatitis B surface antigen with Dynavax's proprietary Toll-like Receptor (TLR) 9 agonist adjuvant CpG 1018 to enhance the immune response. Dynavax has worldwide commercial rights to HEPLISAV-B.