DYNAVAX
DYNAVAX TECHNOLOGIES

DYNAVAX INTERNATIONAL B.V.
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10 February 2014

Dr. Tomas Salmonson
CHMP Chairman
European Medicines Agency
7 Westferry Circus
Canary Wharf
London
E14 4HB
United Kingdom

Subject: Withdrawal of HEPLISAV, (Hepatitis B surface antigen), 20 micrograms, Solution for Injection - EMEA/H/C/2603

Dear Dr. Salmonson,

I would like to inform you that, at this point of time, Dynavax International B.V. ("Dynavax") has taken the decision to withdraw the application for Marketing Authorisation of HEPLISAV (Hepatitis B surface antigen), 20 micrograms, Solution for Injection, which was intended to be used for active immunisation of adults against hepatitis B virus (HBV) infection caused by all known subtypes.

This withdrawal is based on the need for additional clinical data because the current safety database is considered to be too small to rule out a risk of less common serious adverse events. The timeframe provided by the centralized procedure does not permit the collection of the necessary clinical data within this review procedure. However, Dynavax is beginning an additional HEPLISAV trial in North America that is intended to provide a safety database sufficient to support licensure.

There are currently no ongoing clinical trials in the EU or a compassionate use programme for this product. Therefore, there are no anticipated consequences of this withdrawal.

We reserve the right to make further submissions at a future date in this or other therapeutic indications.

I agree for this letter to be published on the EMA website.

Yours sincerely,

Senior Director, Regulatory Affairs
Dynavax International B.V.