New Hep B Vaccine Performs Well in Clinical Trial

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Heplisav, a new hepatitis B virus (HBV) vaccine being development by Dynavax Technologies Corporation, is both well-tolerated and effective, according to clinical trial results published in the journal Vaccine and highlighted in an announcement by the company.

For the study, which enrolled 2,415 participants between 18 and 70 years of age, three-quarters of the volunteers received Heplisav, while the remaining one-quarter of the participants received Engerix-B, an approved vaccine produced by GlaxoSmithKline.

The researchers found that in addition to being well-tolerated by those taking it, HEPLISAV provided a 95 percent seroprotection rate—protections against HBV—as opposed to an 81 percent seroprotection rate for those taking Engerix-B.

As an additional benefit, Heplisav requires only two doses administered one month apart, while vaccines such as Engerix-B and Merck's Recombivax HB require three doses administered over a six-month period.

Dynavax plans to submit a Biologic License Application—an approval request from the U.S. Food and Drug Administration—for Heplisav by May 2012.

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http://beta.docker.hepmag.com/article/Heplisav-Trial-Results-21916-756592733