

# An Observer-blinded, Randomized Study Comparing the Safety and Immunogenicity of HEPLISAV™ to Licensed Vaccine (Engerix-B®) among Adults with Chronic Kidney Disease

Amy Young<sup>1\*</sup>; Lisa Korth<sup>1</sup>; Robert Janssen, MD<sup>2</sup>; William Heyward, MD<sup>2</sup>; J. Tyler Martin, Sr., MD<sup>2</sup>  
(1) DaVita Clinical Research, Minneapolis, MN; (2) Dynavax Technologies Corporation, Berkeley, CA

## INTRODUCTION

Hepatitis B virus (HBV) vaccination is recommended in CKD and ESRD patients due to their defects in humoral and cellular immune responses and potential for higher exposure rates in dialysis clinics. Unfortunately only 2/3 of renal patients achieve seroprotection with the standard vaccine, Engerix-B®. HEPLISAV is an investigational vaccine against HBV infection containing a 22-mer immunostimulatory phosphorothioate oligodeoxyribonucleotide and recombinant HBsAg.

## MAIN STUDY GOAL

To demonstrate the non-inferiority of the immune response to a 3-dose regimen of HEPLISAV vaccination compared to the standard 4-dose regimen of Engerix-B.

## STUDY DESIGN

### Overview

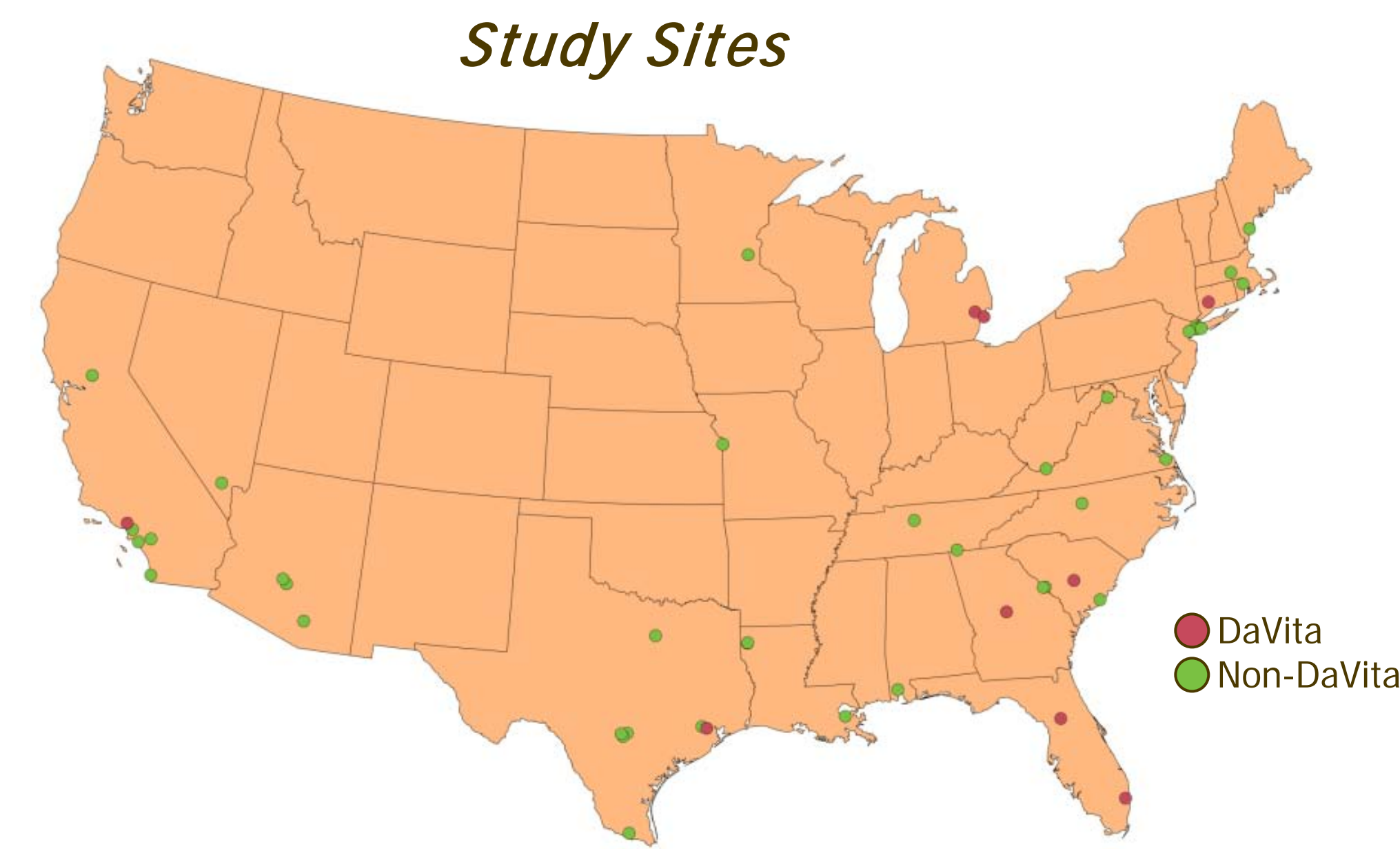
- Phase III study
- Patient participation is 1 year

### Inclusion Criteria

- HBV-vaccine naïve subjects
- 18-75 yrs old
- GFR ≤ 45 mL/min/1.73 m<sup>2</sup>

### Exclusion Criteria

- Subjects cannot:
  - be scheduled to undergo a kidney transplant in the next 12 months of study start,
  - have a history of HBV, HCV or HIV exposure,
  - have a known history of autoimmune disease,
  - be undergoing chemotherapy
  - have uncontrolled diabetes or hypertension



- |                       |                       |                       |
|-----------------------|-----------------------|-----------------------|
| • Mobile, AL          | • Macon, GA           | • Great Neck, NY      |
| • Phoenix, AZ         | • New Orleans, LA     | • Mineola, NY         |
| • Tucson, AZ          | • Shreveport, LA      | • Providence, RI      |
| • Tempe, AZ           | • Worcester, MA       | • Charleston, SC      |
| • Fountain Valley, CA | • Biddeford, ME       | • Orangeburg, SC      |
| • Los Angeles, CA     | • Detroit, MI         | • Chattanooga, TN     |
| • Northridge, CA      | • Pontiac, MI         | • Nashville, TN       |
| • Riverside, CA       | • Brooklyn Center, MN | • Edinburg, TX        |
| • Sacramento, CA      | • Kansas City, MO     | • Fort Worth, TX      |
| • San Diego, CA       | • High Point, NC      | • Houston, TX (2)     |
| • Waterbury, CT       | • Newark, NJ          | • San Antonio, TX (2) |
| • Middlebury, CT      | • Las Vegas, NV       | • Norfolk, VA         |
| • Coral Springs, FL   | • Bronx, NY           | • Winchester, VA      |
| • Ocala, FL           | • Flushing, NY        | • Bluefield, WV       |
| • Evans, GA           |                       |                       |

### Study Enrollment

- Enrollment is ongoing.
- Nine DaVita research sites are participating.
- Site selection is complete for this study.

## CONTACT INFORMATION

- ✓ If you have eligible patients for this study, please visit [www.DaVitaClinicalResearch.com](http://www.DaVitaClinicalResearch.com).
- ✓ For non-DaVita research sites, please contact John at [jenriquez@accelovance.com](mailto:jenriquez@accelovance.com).

## FUNDING INFORMATION

*The study is funded by Dynavax Technologies Corporation.*

We express our sincere appreciation to the teammates in our nearly 1600 clinics who work every day, not only to take care of patients but also to ensure the extensive data collection on which our work is based. We thank DaVita Clinical Research® for support in preparing this poster. DCR is committed to advancing the knowledge and practice of kidney care.

\*Correspondence: [amy.young@davita.com](mailto:amy.young@davita.com)  
American Society of Nephrology RenalWeek 2010, Denver, CO