

A man with short dark hair and a slight smile, wearing a dark jacket over a blue and black striped shirt, stands in a crowd. A black strap is visible over his shoulder. The background is a blurred crowd of people, suggesting a public event or festival.

# DYNΛVAX

We develop and commercialize innovative vaccines

## Corporate Overview

August 2020

Nasdaq: DVAX

A solid green triangle pointing upwards, located in the bottom right corner of the slide.

# Forward-Looking Statements

Statements contained in this presentation regarding matters that are not historical facts are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, including statements about HEPLISAV-B becoming the market leader and standard of care in the U.S., potential market opportunity for HEPLISAV-B in the U.S., China and other countries, the completion of post-marketing studies of HEPLISAV-B, our development of a vaccine for COVID-19, our development and commercialization of an improved pertussis vaccine and other vaccines using our novel adjuvant CpG-1018, and establishing CpG-1018 as a leading adjuvant platform. These forward-looking statements are based upon management’s current expectations, are subject to known and unknown risks, and involve assumptions that may never materialize or may prove to be incorrect. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, including, without limitation, risks related to the continuing impact of COVID-19 on vaccine utilization and sales, including HEPLISAV-B; risks related to the potential adverse effects of the coronavirus pandemic on our ability to access customers and on customer decision making, adoption and implementation; risks related to Dynavax’s ability to successfully commercialize HEPLISAV-B, which among other things will require Dynavax to successfully negotiate and enter into contracts with wholesalers, distributors, group purchasing organizations, and other parties, and maintain those contractual relationships, maintain and build its commercial infrastructure, and access prescribers and other key health care providers to discuss HEPLISAV-B; risks related to market adoption and competing therapies; risks related to whether payors will cover and provide timely and adequate reimbursement for HEPLISAV-B; risks related to the completion, timing of completion and results of post-marketing clinical trials of HEPLISAV-B; risks related to development and commercialization of HEPLISAV-B in Europe, China and other countries; and risks associated with the development and commercialization of vaccines in the U.S. and outside the U.S., including vaccines for COVID-19 and pertussis. These and other risks and uncertainties are described in Dynavax’s Quarterly Report on Form 10-Q for the quarter ended March 31, 2020 and our 10-K for the year ended December 31, 2019, under the heading “Risk Factors”. Dynavax undertakes no obligation to revise or update information herein to reflect events or circumstances in the future, even if new information becomes available.

# Key Drivers of Long-Term Growth

## HEPLISAV-B® U.S. sales

- ✓ Faster and higher rates of protection compared to legacy 3-dose vaccines
- ✓ Positioned to become the standard of care for adults in U.S.
- ✓ Market growth opportunity from increase coverage rates of under vaccinated populations (i.e. people living with diabetes)

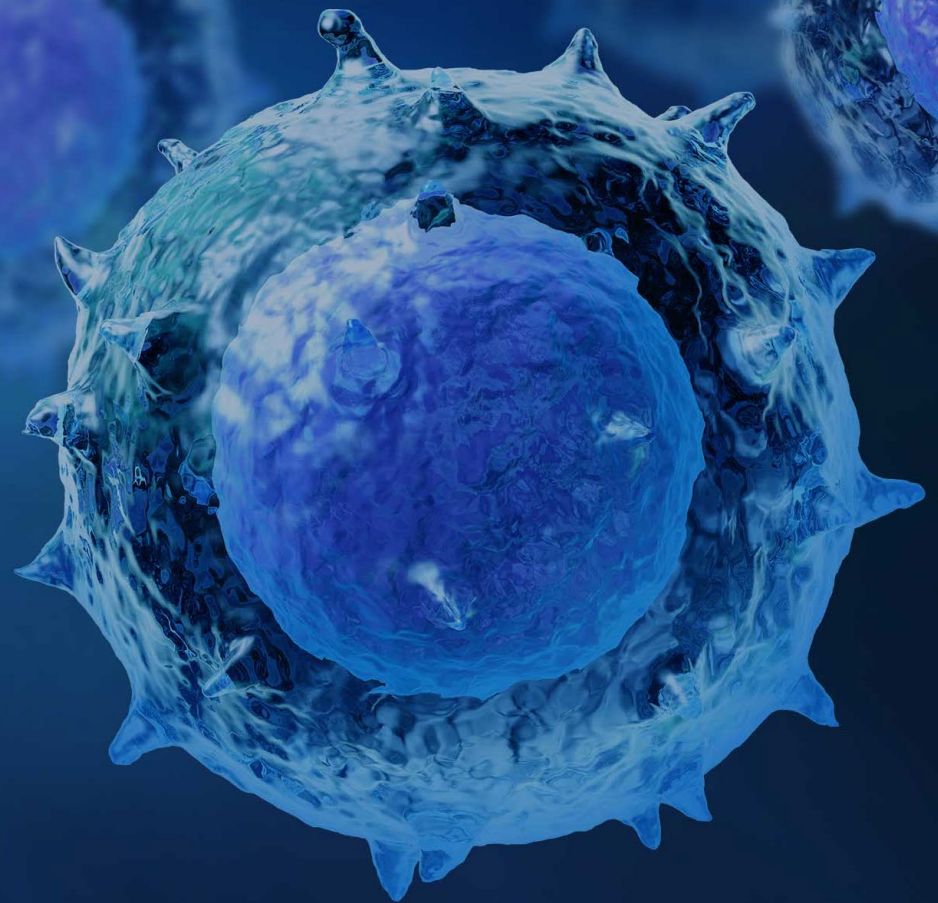
## Capture HEPLISAV-B ex-U.S. value

- ✓ Marketing authorization application filed with European Medicines Agency
- ✓ Substantial opportunity in China

## Leverage CpG 1018™ adjuvant

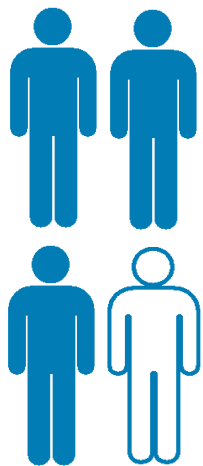
- ✓ Develop CpG 1018 as a broad vaccine adjuvant platform by establishing multiple research collaborations
- ✓ Collaborating with Serum Institute of India on an improved Pertussis vaccine
- ✓ Multiple coronavirus vaccine collaborations – two currently in Phase 1 testing

HEPLISAV-B





# Hepatitis B Infection Can Put Everyone at Risk



Up to

**75%**

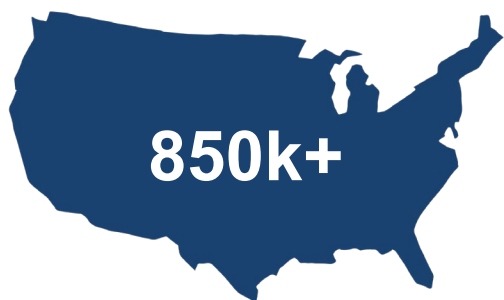
of adults do not  
complete a 3  
dose series



~20% to 30% of  
people failed to  
achieve protective  
immunity after  
completion of  
legacy 3 dose  
product

**~5,500**

HBV related deaths  
occur each year in  
the U.S.



**850k+**

people in the U.S. are  
infected with hepatitis B

**HBV** is **50-100X**

more infectious than

**HIV**



HBV infection rates  
increased **~11%** over  
a 5 year period

# HEPLISAV-B: Changing Adult Hepatitis-B Prevention

## ATTRACTIVE Commercial Profile

1<sup>st</sup>

New hepatitis B  
vaccine in 25 years

HEPLISAV-B	Engerix-B®*
1 month	6-month
2-dose	3-dose

Faster & higher rates of protection  
and similar safety profile



Up to 75% of adults  
do not complete a  
three-dose series

## ESTABLISHED Targeted Market

Field team sized to cover

~70% of the  
target  
market



Highly-experienced  
vaccine sales force to  
drive market uptake

## POTENTIAL Market Expansion



Increase coverage  
rates and drive  
uptake in diabetic  
market

**HEPLISAV-B™**  
Hepatitis B Vaccine (Recombinant), Adjuvanted

Positioned  
to become  
market leader

# Improved Protection with HEPLISAV-B Drives Adoption

## Higher and faster rates of protection

- ✓ HEPLISAV-B provided significantly higher rates of protection than Engerix-B at every time point

## Fewer doses

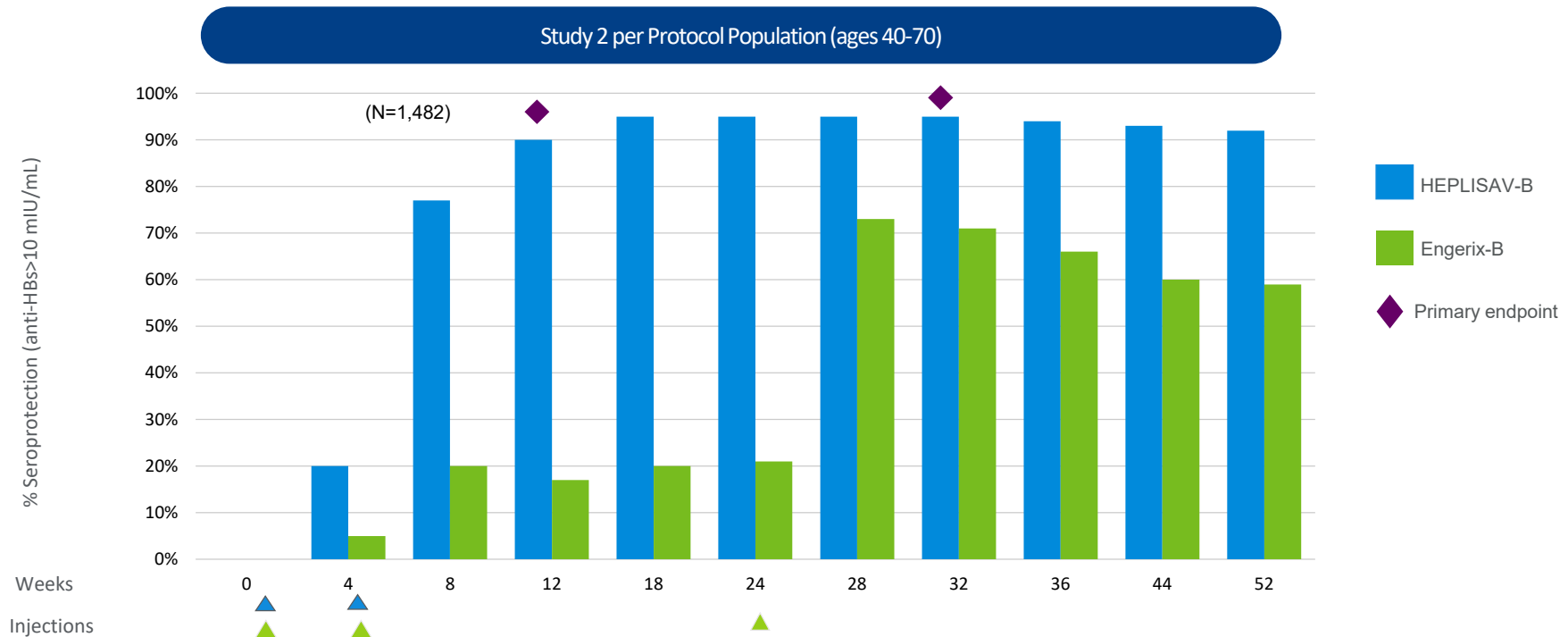
- ✓ HEPLISAV-B can protect with only 2 doses in 1 month

## Protection for patients most at need

- ✓ HEPLISAV-B provided significantly higher rates of protection in diabetics and other known hypo-responsive populations

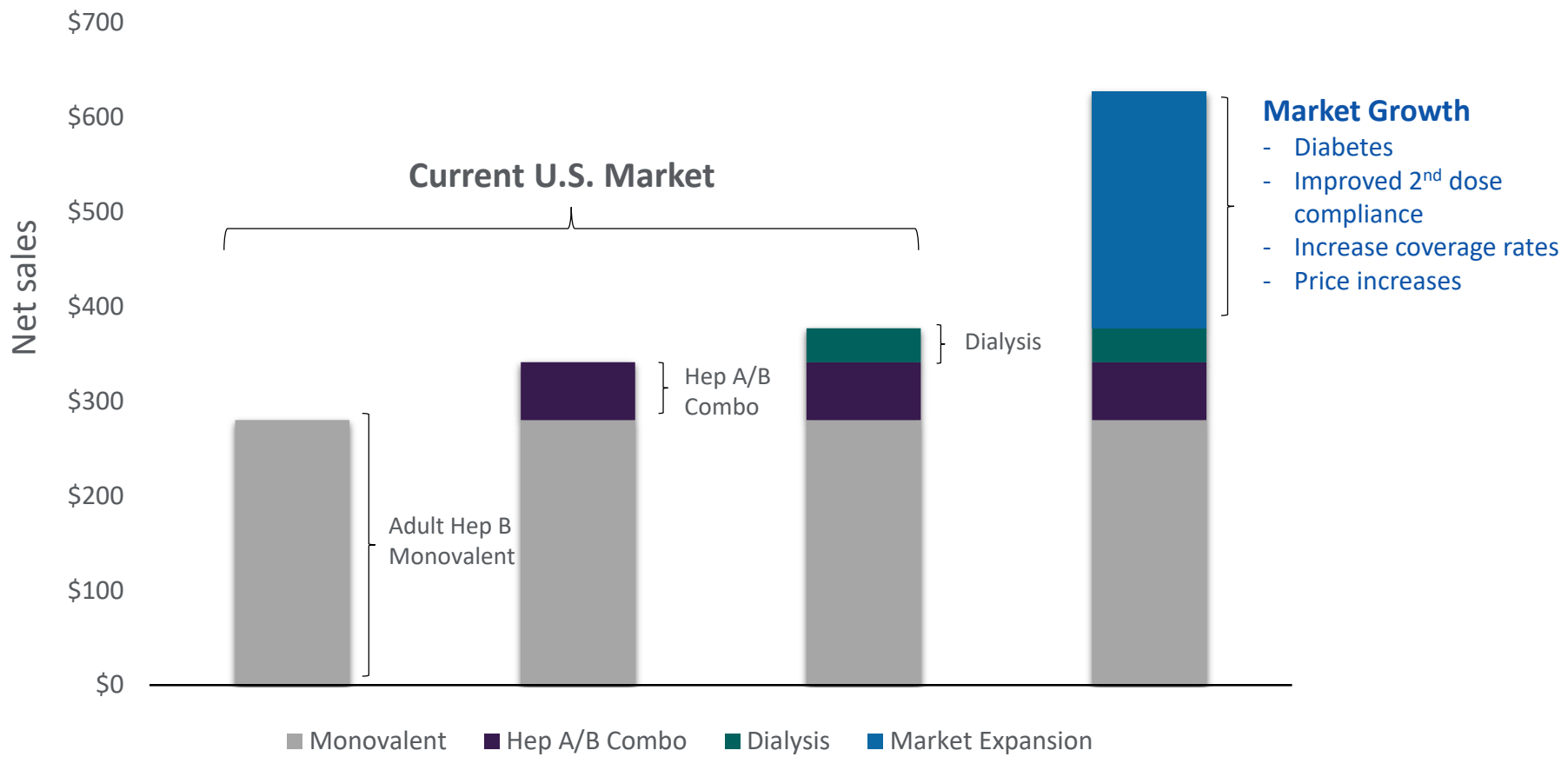
## Favorable safety profile

- ✓ Across clinical trials in nearly 10,000 patients



# Large Market Opportunity with Room to Grow

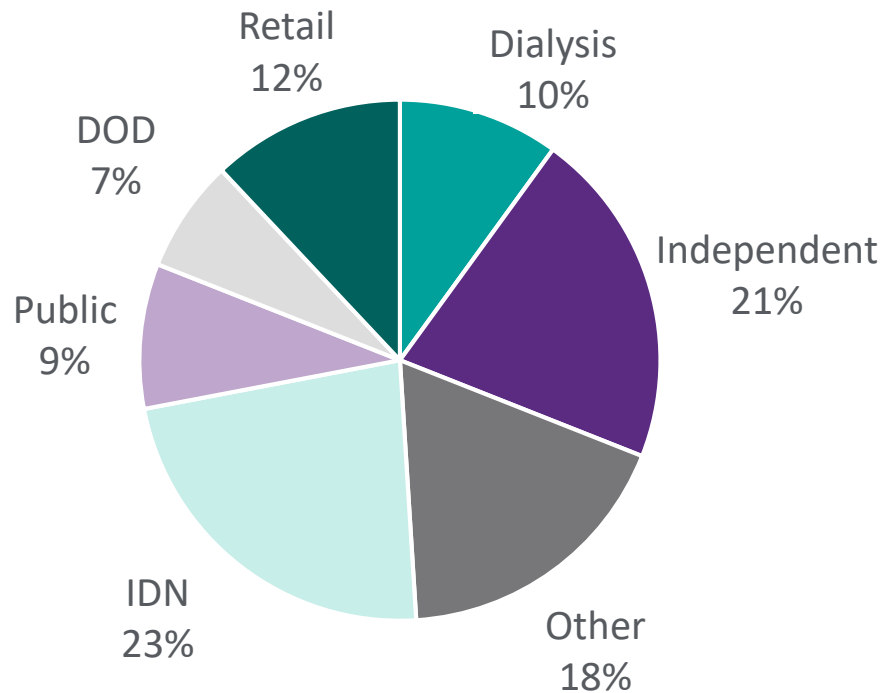
U.S. Adult Hepatitis B Vaccine Market Opportunity Based on HEPLISAV-B Regimen and Price



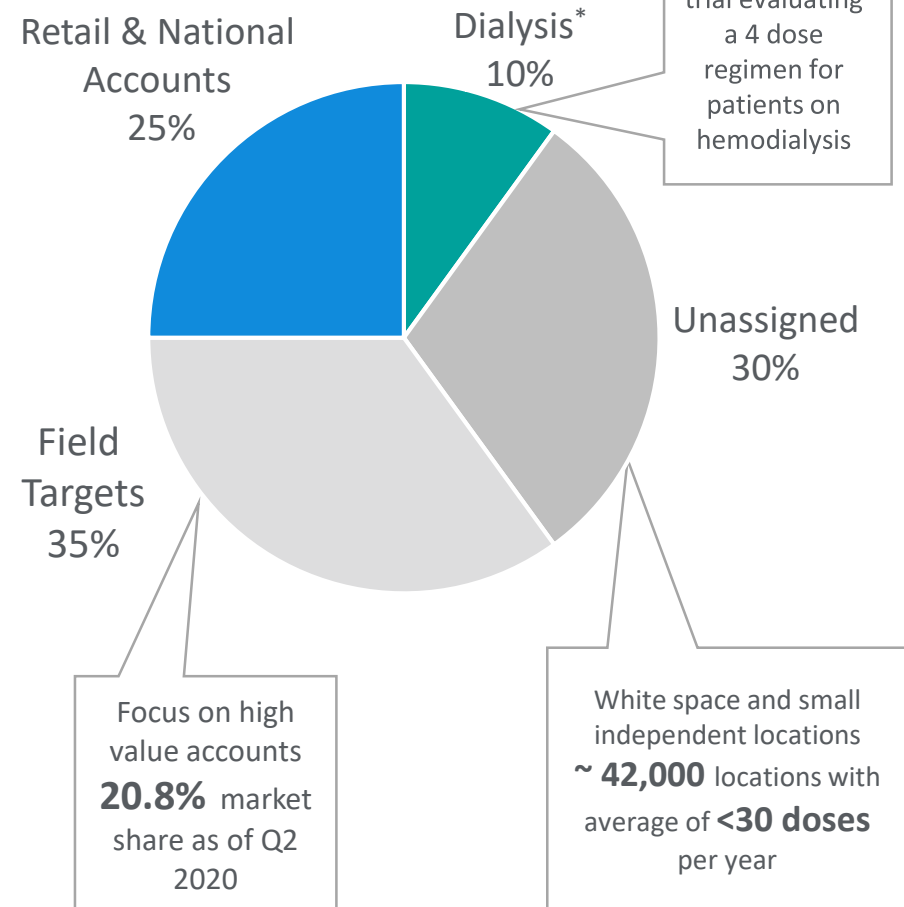


# Right Commercial Strategy to Capture Opportunity

## Total Adult HEPLISAV-B U.S. Market Opportunity by Segment



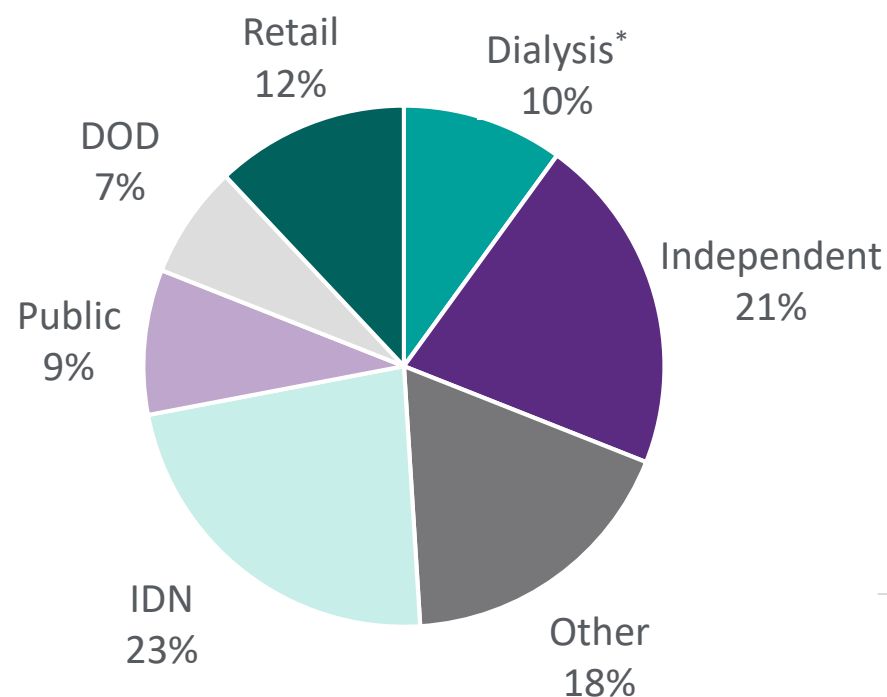
## Total Market by Promotional Opportunity



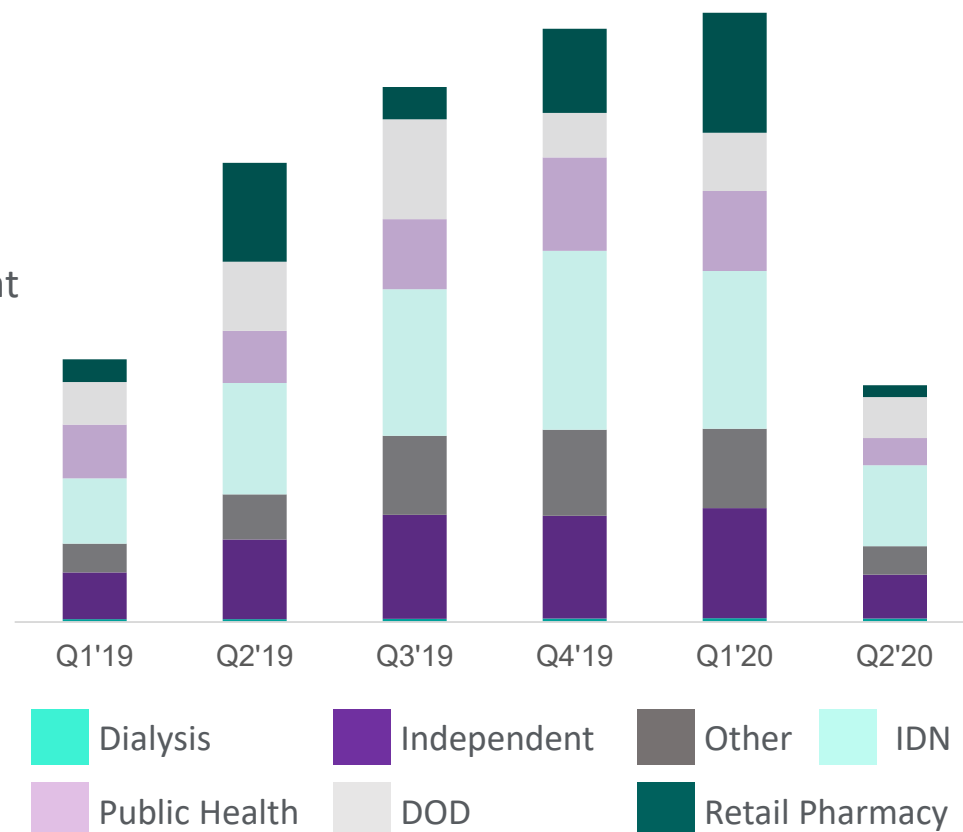
\*Currently no promotional activity in dialysis segment

# Commercial Execution Driving Adoption Across Segments

## Total Adult HEPLISAV-B U.S. Market Opportunity by Segment

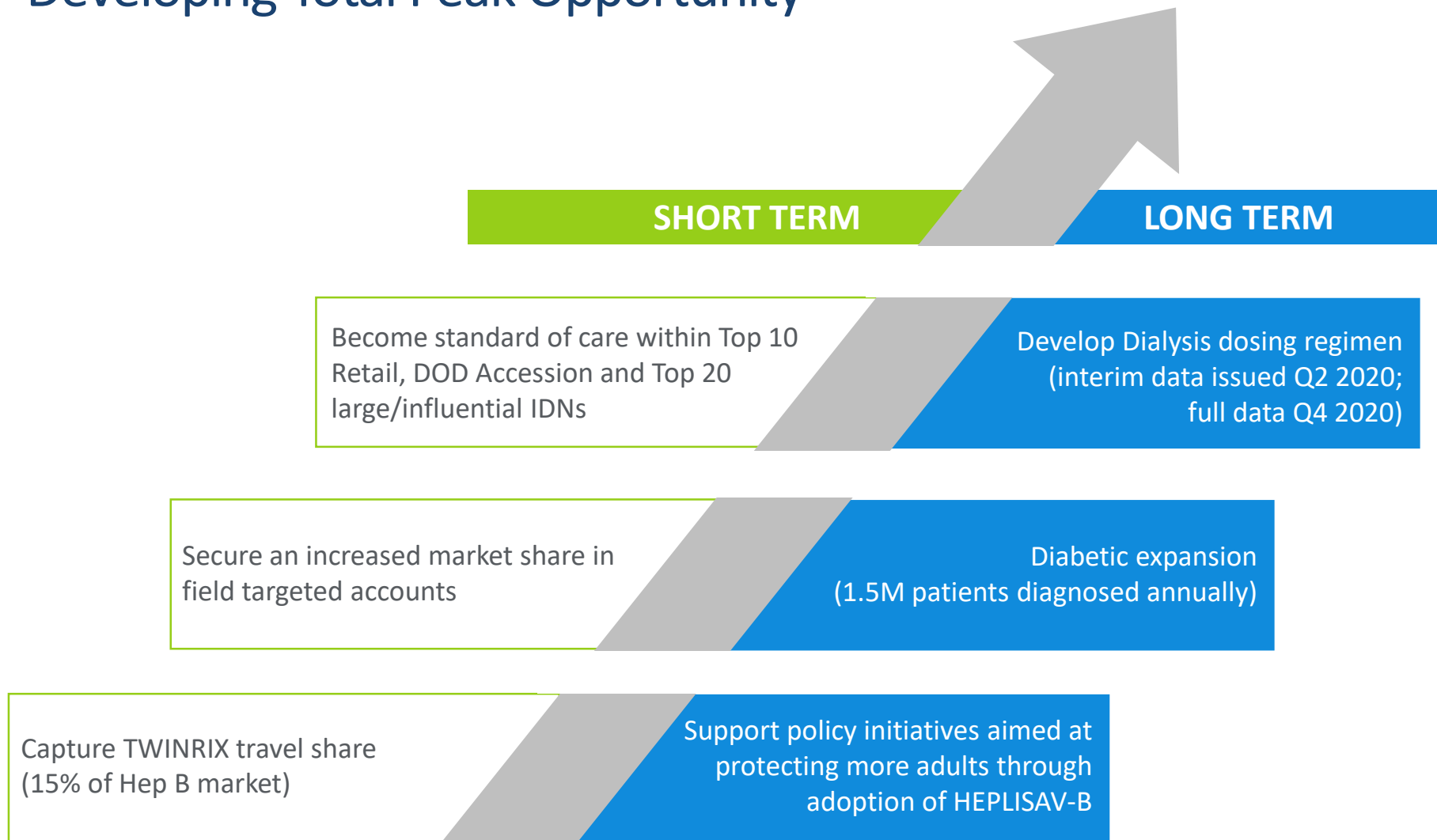


## HEPLISAV-B Doses Sold by Segment



\*Currently no promotional activity in dialysis segment

# Path to Capturing the Current Market and Developing Total Peak Opportunity



CpG-1018



# CpG 1018 – Advanced Vaccine Adjuvant Platform

- Well-defined mechanism of action
  - Targeting select immune system cells, with well-characterized effects on the immune response
  - Mimicking the immune response to naturally occurring TLR9 agonists in pathogens, resulting in potent adjuvant activity for antibody responses
- As the adjuvant in an FDA approved product, CpG 1018 offers an established profile for the development of a safe and effective vaccine
  - In HEPLISAV-B CpG 1018 drives faster and consistently higher rates of protection including the elderly and populations known to be less responsive to other vaccines
  - CpG 1018 differentially elicits a preferred Th1 polarized response driving both production of antibodies and T-cell activation
  - Potential for dose sparing of vaccine antigen resulting in greater availability of supply
- Focus areas for pre-clinical research:
  - Pandemic use
    - Coronaviruses, pandemic influenza, future emerging pandemic viruses
  - Broad vaccine adjuvant platform
    - For disease targets where no vaccine exists, or a better one is needed

# CpG 1018 Collaboration Pipeline

Multiple “shots on goal” for CpG 1018 in vaccine product candidates

	Collaborator	Indication	Status	Upcoming Milestone
Inactivated Virus	Sinovac Biotech	COVID-19	Preclinical	
	Valneva		Preclinical	Goal to initiate clinical trials before end of 2020 (subject to successful preclinical work and receipt of appropriate funding)
VLP	Medicago		Phase 1	Preliminary safety and immunogenicity results expected in October
Protein Sub-Unit	Clover Bio		Phase 1	Preliminary safety and immunogenicity results expected in September
	Medigen	Pertussis	Preclinical	Phase 1 trial to begin in Q3
	Serum Institute of India		Preclinical	Completion of Phase 1-enabling animal studies and toxicology
	Mount Sinai	Universal flu	Preclinical	Phase I clinical trials to begin soon

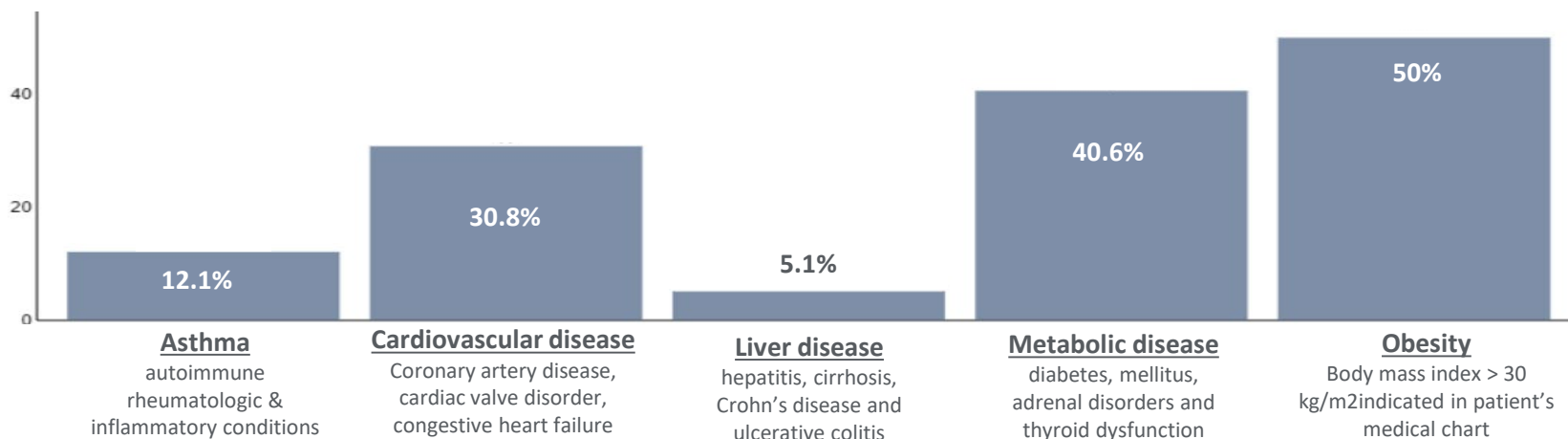
Additional collaborations anticipated to be announced by year end for COVID-19 and other indications



# COVID-19 Patients With Preexisting Conditions

There is an unprecedented need to develop, manufacture, test and distribute safe and effective vaccines to fully control the COVID-19 pandemic

- Patients with preexisting conditions are 6-7 times more likely to be hospitalized and more than 10X more likely to die than patients without preexisting conditions
- Among 10,687 hospitalized adults with information on underlying medical conditions, 90.8% had at least one reported underlying medical condition. The most commonly reported were hypertension, obesity, chronic metabolic disease and cardiovascular disease.

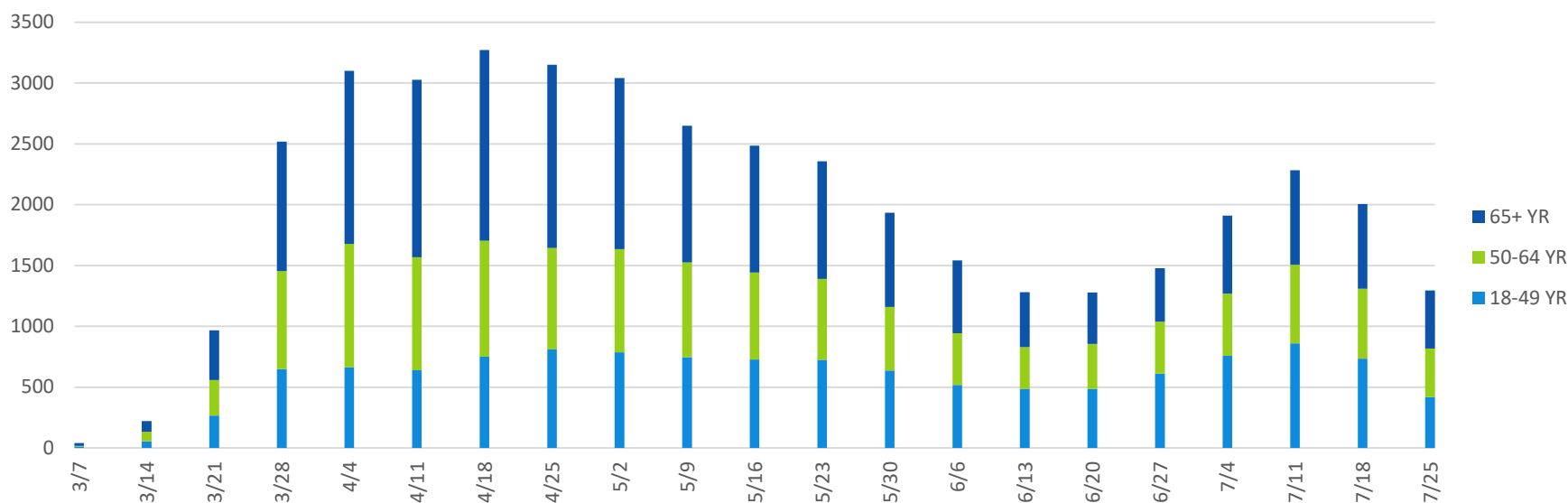


The coronavirus Disease 2019 associated hospitalization surveillance network hospitalization data are preliminary and subject to change as more data becomes available. In particular, case counts and rates for recent hospital admissions are subject to lag. As data are received each week prior case counts and rates are updated accordingly. COVID-NET conducts population-based surveillance for laboratory-confirmed COVID-19-associated hospitalizations in adults. COVID-NET covers nearly 100 counties in the 10 emerging infections program (EIP) states (CA, CO, CT, GA, MD, MA, NM, NY, OR, TN) and four influenza hospitalization surveillance project (IHSP) states (IA, MI, OH, and UT). Incidence rates (per 100,000 population) are calculated using the NCHS vintage 2018 bridged-race postcensal population estimates for the counties included in the surveillance catchment area. The rates provided are likely to be underestimated as COVID-19 hospitalizations might be missed due to test availability and provider or facility testing practices.

# COVID-19 Associated Hospitalization by Age

Patients aged 60+ account for ~60% of hospital and ICU admissions and ~90% of deaths while representing 20% of population

- A total of 42,403 laboratory-confirmed COVID-19-associated hospitalizations were reported by sites between March 1, 2020 and July 25, 2020. The overall cumulative hospitalization rate was 130.1 per 100,000 population. Among the 18-49 years, 50-64 years, and  $\geq 65$  years age groups, the highest rate of hospitalization was among adults aged  $\geq 65$ , followed by adults aged 50-64 years and adults aged 18-49 years.



Counts of COVID-19-associated Hospitalizations by Age from the COVID-NET Network as of July 25

## Collaboration With Serum Institute of India (SII) for Pertussis (Tdap-1018)

Agreement to provide SII with CpG 1018 and technical support to develop and commercialize an improved adjuvanted pertussis vaccine and other vaccines

- A higher immune response resulting in increased duration of protection,
- Reducing colonization, thus reducing or preventing person to person transmission



Preclinical testing ongoing;  
data expected Q4 2020

# Collaboration with Mount Sinai for Universal Flu

The Mount Sinai CIVICs team will evaluate a novel approach they have developed called chimeric hemagglutinin (cHA) designed to protect against all strains of influenza in combination with Dynavax's CpG 1018 adjuvant.

Mount Sinai's current work in this area is funded under a contract award from the National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH), as part of the Collaborative Influenza Vaccine Innovation Centers (CIVICs) program established by NIAID.



The development program will support an Investigational New Drug (IND) application for Phase I clinical trials.

# 2020 Goals

- **Grow HEPLISAV-B U.S. Sales**

- ✓ Released interim data from ongoing study of HEPLISAV-B in patients on hemodialysis in Q2 2020
- Final hemodialysis immunogenicity data in the second half of 2020
- Complete safety follow-up for HEPLISAV-B post-marketing studies in Q4 2020

- **Capture HEPLISAV-B ex-U.S. Value**

- Advance review of MAA for target approval in Q1 2021
- Assess ex-U.S. and China opportunities to expand HEPLISAV-B revenue opportunities

- **Expand Product Opportunities**

- Complete Phase 1 enabling animal studies and toxicology for improved pertussis vaccine with CpG 1018
- ✓ Support multiple collaborators to develop a vaccine candidate to protect against COVID-19 – Anticipate CpG 1018 to be included in at least one coronavirus vaccine clinical trial as soon as July 2020
- ✓ Enter multiple strategic relationships focused on initial research in a variety of vaccine candidates to establish CpG 1018 as a leading adjuvant

# Dynavax – Key Takeaways

- The current global focus on infectious diseases, preparedness and prevention reinforces Dynavax's core business and has enhanced long-term drivers of growth
- Vaccines are a valuable long-term business with steady, recurring revenue
- Dynavax is focused on leveraging its key assets - HEPLISAV-B, CpG 1018 and its vaccine development and commercialization expertise to drive shareholder value
- HEPLISAV-B is well positioned to capture a majority of the U.S. hepatitis B market and become the standard of care for adults in the U.S.
- CpG 1018 is a proven adjuvant technology with a significant safety database providing a platform for the development of new and improved vaccines
- Coronavirus pandemic has created multiple potential long-term drivers of growth



# DYNAVAX

Protection for an  
unpredictable world



Thank you