Dynavax Highlights 2022 Priorities and Announces Initiation of Phase 1 Clinical Trial for Its Shingles Vaccine Candidate

January 10, 2022

- Dynavax expects year over year revenue growth for HEPLISAV-B and CpG 1018 adjuvant to drive continued profitability in 2022

- Strong financial position supports investment in long-term growth drivers including pipeline expansion

- Initiation of Phase 1 clinical trial of shingles vaccine candidate, adjuvanted with CpG 1018, with data expected year end 2022

EMERYVILLE, Calif., Jan. 10, 2022 /PRNewswire/ -- Dynavax Technologies Corporation (Nasdaq: DVAX), a commercial stage biopharmaceutical company focused on developing and commercializing innovative vaccines, today outlined its strategic priorities for 2022, and announced the newest candidate in its clinical development portfolio – a herpes zoster virus (shingles) vaccine candidate.

"The transformative increase in value we saw in 2021 resulted from the strategic realignment of our company to focus on vaccines, driving growth in HEPLISAV-B® and advancing our CpG 1018® adjuvant supply strategy with a diverse portfolio of COVID-19 vaccine developers," said Ryan Spencer, Chief Executive Officer of Dynavax. "We anticipate continued product revenue growth in 2022 which will further enable investment in our clinical pipeline leveraging our proven adjuvant technology and help fuel our vision to build a leading vaccine company."

Strategic Priorities to Drive Long-term Growth

Dynavax anticipates continued profitability in 2022 driven by its CpG 1018 adjuvant supply business for COVID-19 vaccines and increasing HEPLISAV-B sales. To help achieve its long-term growth strategy, the Company's strategic priorities for 2022 include:

Maximize Growth of HEPLISAV-B [Hepatitis B Vaccine (Recombinant), Adjuvanted]

- Recently upgraded recommendations from the CDC's Advisory Committee on Immunization Practices advise that all adults aged 19-59 be vaccinated against Hepatitis-B, creating a significantly expanded market opportunity which the company estimates to be $800 million in the U.S. by 2027. The Company believes that HEPLISAV-B is well-positioned to secure majority market share.
- With a proven clinical profile and strong commercial execution, the Company expects further market share gains and revenue growth in 2022.

Expand CpG 1018 Adjuvant Supply Business for COVID-19 Vaccines

- Recent Phase 3 clinical data from partnered programs consistently demonstrated the value of CpG 1018 adjuvant across multiple vaccine platforms.
- Additional regulatory authorization for partners' COVID-19 vaccines anticipated in the first half of 2022.
- Dynavax continues to expand manufacturing capacity to meet our partners' needs for adjuvant in 2022 and beyond.

Drive Innovation Through Clinical Pipeline Expansion and Discovery

- Topline data is expected in the first half of 2022 from the Company's ongoing Tdap-1018 phase 1 clinical trial evaluating the safety, tolerability, and immunogenicity in adults with adolescent data expected in the second half of 2022.
- Topline data from a phase 1 clinical trial evaluating the safety, tolerability, and immunogenicity of the Company's investigational shingles vaccine candidate adjuvanted with CpG 1018 is expected by the end of 2022.
- In collaboration with, and fully funded by, the U.S. Department of Defense, the company will conduct a phase 2 clinical trial for a plague vaccine adjuvanted with CpG 1018 which is anticipated to initiate in the second half of 2022.
- Further advancement of product candidates with CpG 1018 adjuvant through pre-clinical and clinical collaborations and additional discovery efforts, including ongoing partnership with Mount Sinai investigating universal and seasonal influenza.

CpG 1018 Adjuvanted Shingles (Herpes Zoster) Vaccine Candidate Enters the Clinic

Shingles is an extremely painful consequence of the reactivation of a latent varicella zoster virus infection, with attacks leading to potential complications including chronic pain. The current shingles vaccine market is approximately $2 billion and expected to grow over time.

"Our CpG 1018 adjuvant has an established tolerability profile demonstrated in a wide range of clinical trials and real-world, commercial use," commented Rob Janssen, Chief Medical Officer of Dynavax. "We therefore believe it is the ideal adjuvant to maintain high levels of efficacy with significantly less reactogenicity resulting in an improved shingles vaccine."

CpG 1018 adjuvant has demonstrated its ability to enhance the immune response without excessive reactogenicity in both HEPLISAV-B and multiple COVID-19 clinical trials. Importantly, CpG 1018 has shown the ability to generate high levels of CD4+ t-cells which have been demonstrated to be key cell types in controlling latent VZV infection to avoid reactivation leading to shingles. The global phase 1 study is designed to evaluate safety, tolerability and immunogenicity of the vaccine candidate which is comprised of glycoprotein E (gE) plus CpG 1018 adjuvant. Data from this trial is expected to be available by the end of 2022.

About Dynavax
Dynavax is a commercial stage biopharmaceutical company developing and commercializing novel vaccines to help protect the world against infectious diseases. The Company's first commercial product, HEPLISAV-B® [Hepatitis B Vaccine (Recombinant), Adjuvanted], is approved in the U.S. and the European Union for prevention of infection caused by all known subtypes of hepatitis B virus in adults age 18 years and older. Dynavax is also advancing CpG 1018 adjuvant as a premier vaccine adjuvant through research collaborations and partnerships. Current collaborations are focused on adjuvanted vaccines for COVID-19, plague, Tdap, seasonal influenza and universal influenza. For more information, visit www.dynavax.com and follow the company on LinkedIn.

Forward-Looking Statements
This press release contains "forward-looking" statements, including statements regarding expected or anticipated financial performance, including market share, revenue and profitability, potential U.S. market for hepatitis vaccines, establishing CpG 1018 as a leading adjuvant, the development and potential approval of vaccines containing CpG 1018 by us or by our collaborators, potential market size and future sales of CpG 1018 or HEPLISAV-B or other product candidates, the timing of initiation and completion of clinical studies and the publication of results, the timing of our collaborators seeking conditional, emergency use or full authorization of COVID-19 vaccines containing CpG 1018 adjuvant, our ability to scale manufacturing capacity, our efforts to develop an improved pertussis and shingles vaccine, our collaboration partners' efforts to develop and commercialize a vaccine for COVID-19, entering into strategic relationships and expected results of such relationships and the potential for CpG 1018 to accelerate development and large scale manufacturing of COVID-19 or other vaccines. Actual results may differ materially from those set forth in this press release due to the risks and uncertainties inherent in our business, including, the risk that HEPLISAV-B may not become the standard of care adult hepatitis B vaccine in the U.S., risks related to whether and when prescribers and other key decision-makers at potential purchasing entities will make the decision to switch to HEPLISAV-B, and the timing and quantity of actual purchases, risks related to the timing and impact of the ACIP universal hepatitis B recommendation, risks related to the timing of completion and results of current clinical studies conducted by us or our collaborators, risks that our collaborators will not obtain approval of their vaccine candidates, risks related to the development and pre-clinical and clinical testing of vaccines containing CpG 1018 adjuvant, and whether use of CpG 1018 will prove to be beneficial in these vaccines, risks related to whether, when and the quantity of CpG 1018 actually purchased by vaccine companies, risks related to the use of contract manufacturers to timely supply CpG 1018 and financial commitments made to them, as well as other risks detailed in the "Risk Factors" and "Management's Discussion of Financial Condition and Results of Operations" sections of our Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2021 and periodic filings made thereafter, as well as discussions of potential risks, uncertainties and other important factors in our other filings with the U.S. Securities and Exchange Commission. We undertake no obligation to revise or update information herein to reflect events or circumstances in the future, even if new information becomes available.

Information on Dynavax's website at www.dynavax.com is not incorporated by reference in our current periodic reports with the SEC.

Contacts:
Nicole Arndt, Investor Relations
narndt@dynavax.com
510-665-7264

Derek Cole, President
Investor Relations Advisory Solutions
derek.cole@IRadvisory.com

View original content to download multimedia:https://www.prnewswire.com/news-releases/dynavax-highlights-2022-priorities-and-announces-initiation-of-phase-1-clinical-trial-for-its-shingles-vaccine-candidate-301457026.html

SOURCE Dynavax Technologies