Dynavax Announces Preliminary Unaudited Fourth Quarter and Full Year 2022 Financial Highlights and Phase 1 Shingles Topline Results

January 9, 2023

- **Preliminary full year 2022 HEPLISAV-B® vaccine Net Product Revenue of approximately $126 million, representing 104% growth compared to 2021**
- **Preliminary full year CpG 1018® adjuvant Net Product Revenue of approximately $588 million**
- **Maintained strong financial position with year-end cash and investments of approximately $624 million**
- **Phase 1 shingles trial results demonstrate favorable tolerability with similar vaccine response rates in CpG 1018 adjuvanted arms versus comparator vaccine**

EMERYVILLE, Calif., Jan. 9, 2023 /PRNewswire/ -- Dynavax Technologies Corporation (Nasdaq: DVAX), a commercial-stage biopharmaceutical company focused on developing and commercializing innovative vaccines, today announced preliminary, unaudited financial highlights for the fourth quarter and full year ending December 31, 2022 and Phase 1 shingles topline results.

"We are pleased with the relentless execution of our strategy throughout 2022, delivering transformative progress across our commercial and development portfolio including revenue at the top end of our guidance, achievement of all of our stated clinical milestones and the strengthening of our balance sheet," said Ryan Spencer, Chief Executive Officer of Dynavax. "In 2023, we anticipate building on the strong foundation laid in 2022, with continued product revenue growth for HEPLISAV-B, advancement of our clinical development pipeline leveraging our versatile CpG 1018 adjuvant technology and execution of our corporate development objectives to help drive long-term value."

2022 Preliminary Unaudited Commercial and Financial Highlights:

- Preliminary HEPLISAV-B Net Product Revenue for the fourth quarter and full year 2022 were approximately $35 million and $126 million, respectively, representing quarterly and annual growth of 105% and 104% compared to Q4 2021 and full year 2021, respectively.
- Preliminary CpG 1018 adjuvant Net Product Revenue for the fourth quarter and full year 2022 were approximately $147 million and $588 million, respectively, representing the successful completion of all pandemic adjuvant delivery obligations under existing commercial supply agreements.
- Approximately $624 million in estimated Cash and Cash Equivalents, and Marketable Securities as of December 31, 2022.

The preliminary selected financial results contained herein are unaudited, subject to adjustment, and provided as an estimate in advance of the Company's announcement of complete financial results for the three and twelve months ended December 31, 2022.

Phase 1 Topline Results from Shingles Program

The Phase 1 clinical trial (DV2-ZOS-01) was designed to evaluate an investigational shingles vaccine Z-1018, utilizing different regimens of CpG 1018 adjuvant, with or without aluminum hydroxide (alum). The trial compared Z-1018 arms versus the active comparator Shingrix®. The Company reported the following topline results, assessed at Week 12, and plans to submit an abstract for presentation at an upcoming medical meeting in the first half of 2023.

- Z-1018 demonstrated high antibody and CD4 positive T-cell vaccine response rates in all arms, which were similar to the comparator;
- Robust increases in CD4 positive T-cells were observed in all Z-1018 arms, although lower than the comparator;
- Total frequency of solicited systemic adverse events and local post-injection reactions were similar across the Z-1018 arms and lower than the comparator,
    - The frequency of moderate and severe local post-injection reactions was 9% for Z-1018 arms compared to 37% for the comparator and the frequency of moderate and severe solicited systemic adverse events was 26% for Z-1018 arms and 43% for the comparator;

"With these promising data, we have a better understanding of the potential for a CpG 1018 adjuvanted shingles vaccine to reduce post-injection reactions to improve patients' experience compared with the currently commercialized shingles vaccine," said Dr. Robert Janssen, Chief Medical Officer of Dynavax. "With the high vaccine response rate, and in comparison with immunologic and efficacy data from previous shingles vaccine studies, we believe our vaccine candidate has the potential to be highly efficacious."

Based on these initial data, the Company intends to advance its shingles vaccine candidate with CpG 1018 adjuvant into a Phase 1-2 study in early

2024 to expand on these results and to evaluate various dose levels of Dynavax-manufactured gE protein.

About DV2-ZOS-01 Clinical Trial

DV2-ZOS-01 is a randomized, active-controlled, dose-escalation, multi-center Phase 1 clinical trial to evaluate the safety, tolerability, and immunogenicity of investigational herpes zoster (shingles) vaccine utilizing a commercially available gE plus CpG 1018 adjuvant (Z-1018) with and without alum compared to Shingrix® in approximately 150 healthy volunteers between the ages of 50 and 69 years of age.

For additional information about this trial, please visit www.clinicaltrials.gov using the identifier NCT05245838.

Shingrix® is a registered trademark of GlaxoSmithKline, PLC.

About HEPLISAV-B

Important U.S. Product Information
HEPLISAV-B is indicated for the prevention of infection caused by all known subtypes of hepatitis B virus in adults aged 18 years and older.

For full U.S. Prescribing Information for HEPLISAV-B, click here.

Important U.S. Safety Information (ISI)
Do not administer HEPLISAV-B to individuals with a history of a severe allergic reaction (e.g., anaphylaxis) after a previous dose of any hepatitis B vaccine or to any component of HEPLISAV-B, including yeast.

Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of HEPLISAV-B.

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to HEPLISAV-B.

Hepatitis B has a long incubation period. HEPLISAV-B may not prevent hepatitis B infection in individuals who have an unrecognized hepatitis B infection at the time of vaccine administration.

The most common patient-reported adverse reactions reported within 7 days of vaccination were injection site pain (23% to 39%), fatigue (11% to 17%), and headache (8% to 17%).
Dynavax

About Dynavax

Dynavax (Nasdaq: DVAX) is a commercial-stage biopharmaceutical company developing and commercializing innovative vaccines to help protect the world against infectious diseases. The Company has two commercial products, HEPLISAV-B® vaccine [Hepatitis B Vaccine (Recombinant), Adjuvanted], which is approved in the U.S. and the European Union for the prevention of infection caused by all known subtypes of hepatitis B virus in adults 18 years of age and older, and CpG 1018® adjuvant, currently used in multiple adjuvanted COVID-19 vaccines. Dynavax is advancing CpG 1018 adjuvant as a premier vaccine adjuvant through global research collaborations and partnerships. Current collaborations are focused on adjuvanted vaccines for COVID-19, seasonal influenza, universal influenza, plague, shingles and Tdap. 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, future sales of CpG 1018 or HEPLISAV-B or other product candidates, anticipated timing and progress of the DV2-ZOS-01 clinical trial and related data analysis, data preparation and publication, the timing of a Phase 1/2 trial for the shingles vaccine candidate or other candidates. 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 related to the development and pre-clinical and clinical testing of vaccines containing CpG 1018 adjuvant, and whether use of CpG 1018 adjuvant will prove to be beneficial in these vaccine candidates, risks related to whether, risks related to the use of contract manufacturers to timely supply CpG 1018 adjuvant 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, 2022 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.

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-announces-preliminary-unaudited-fourth-

quarter-and-full-year-2022-financial-highlights-and-phase-1-shingles-topline-results-301716193.html

SOURCE Dynavax Technologies