Dynavax Announces Preliminary Unaudited Fourth Quarter and Full Year 2024 Financial Highlights

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- *Preliminary 2024 HEPLISAV-B® net product revenue grew 26% year-over-year to approximately $268 million*
- *Enrollment completed in Phase 1/2 shingles trial; top line results expected in Q3 2025*
- *New $30 million contract with U.S. Department of Defense to advance plague vaccine program*
- *Cash, cash equivalents and marketable securities were approximately $714 million as of December 31, 2024*

EMERYVILLE, Calif., Jan. 13, 2025 /PRNewswire/ -- Dynavax Technologies Corporation (Nasdaq: DVAX), a commercial-stage biopharmaceutical company developing and commercializing innovative vaccines, today announced preliminary, unaudited financial highlights for the fourth quarter and full year ended December 31, 2024.

"We are excited to announce that HEPLISAV-B has achieved record annual revenue in 2024, reflecting 26% growth year-over-year, and positioning us at the upper tier of our updated guidance range. This sustained top-line growth not only underscores the strength of the HEPLISAV-B brand, but also lays a strong foundation for long-term value creation. Our robust financial position empowers us to advance our pipeline programs, maintain our focus on achieving recurring profitability, and return capital to our shareholders through an active share repurchase program," said Ryan Spencer, Chief Executive Officer of Dynavax. "Looking ahead to 2025, we are committed to executing our strategic growth pillars, which are centered on maximizing the HEPLISAV-B opportunity, delivering on our clinical pipeline, and pursuing external opportunities to generate sustainable value for our shareholders."

Business Updates and Upcoming Milestones

HEPLISAV-B® [Hepatitis B Vaccine (Recombinant), Adjuvanted]
HEPLISAV-B vaccine is the first and only adult hepatitis B vaccine approved in the U.S., the European Union and Great Britain that enables series completion with only two doses in one month. Hepatitis B vaccination is universally recommended for adults aged 19-59 in the U.S.

- HEPLISAV-B achieved preliminary net product revenue of $268 million for the full year 2024, an increase of 26% compared to $213 million for the full year 2023.
- HEPLISAV-B achieved preliminary quarterly net product revenue of $71 million for the fourth quarter of 2024, an increase of 39% compared to $51 million for the fourth quarter of 2023.
- Dynavax continues to expect the hepatitis B adult vaccine market in the U.S. to expand to a peak of over $900 million in annual sales by 2030, with HEPLISAV-B expected to achieve at least 60% total market share. Additionally, Dynavax believes the HEPLISAV-B U.S. market opportunity will remain substantial beyond 2030 due to the ongoing penetration of the unvaccinated eligible adult population, observed revaccination practices by healthcare providers, and continued gains in market share.

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, 2024.

Clinical Pipeline
Dynavax is advancing a pipeline of differentiated product candidates that leverage its CpG 1018® adjuvant, which has demonstrated its ability to enhance the immune response with a favorable tolerability profile in a wide range of clinical trials and real-world commercial use.

HEPLISAV-B for Adults on Hemodialysis:
Dynavax is developing a four-dose HEPLISAV-B® vaccine regimen for adults on hemodialysis.

- In the fourth quarter of 2024, Dynavax received feedback from the FDA regarding the potential to conduct an observational retrospective cohort study to support its sBLA filing for adults on hemodialysis.

Shingles vaccine program:
Z-1018 is an investigational vaccine candidate being developed for the prevention of shingles in adults aged 50 years and older.

- Dynavax is currently conducting a randomized, active-controlled, dose escalation, multicenter Phase 1/2 trial to evaluate the safety, tolerability, and immunogenicity of Z-1018 compared to Shingrix® in 441 healthy adults aged 50 to 69.
- In the fourth quarter of 2024, the Company completed enrollment in the trial, and Dynavax anticipates reporting top line immunogenicity and safety data in the third quarter of 2025.

Plague vaccine program:

Dynavax is developing a plague (rF1V) vaccine candidate adjuvanted with CpG 1018® in collaboration with, and fully funded by, the U.S. Department of Defense (DoD).

- Based on the results from a randomized, active-controlled Phase 2 clinical trial of the plague vaccine adjuvanted with CpG 1018, Dynavax and the DoD executed a new agreement for approximately $30 million through the first half of 2027 to support additional Phase 2 clinical and manufacturing activities.

WHAT IS HEPLISAV-B?
HEPLISAV-B is a shot given to adults 18 years of age and older to help prevent infection caused by the hepatitis B virus. HEPLISAV-B is usually given in the arm muscle. HEPLISAV-B is given in 2 doses, 1 month apart, by a healthcare provider.

IMPORTANT SAFETY INFORMATION
If you have a history of severe allergic reaction after a previous dose of any hepatitis B vaccine, or to any ingredient of HEPLISAV-B, including yeast, do not take HEPLISAV-B.

HEPLISAV-B must be given by a medical professional, who will monitor you afterwards, to check for allergic reaction.

If you are immunocompromised, or receiving immunosuppressant therapy, you may have less of an immune response to HEPLISAV-B.

Some people have hepatitis B infection without being aware of it or showing any symptoms. If you already have hepatitis B present in your body, HEPLISAV-B may not prevent hepatitis B infection.

The most common side effects include pain at the injection site, tiredness, and headache.

HEPLISAV-B was not studied in pregnant or nursing women. Tell your provider if you are pregnant or plan to become pregnant or are breast feeding.

Vaccination with HEPLISAV-B may not protect all individuals.

Talk to your healthcare provider to determine if HEPLISAV-B is right for you.
Please see full Prescribing Information

About Dynavax
Dynavax 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., the European Union and Great Britain 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 HEPLISAV-B and multiple adjuvanted COVID-19 vaccines. For more information about our marketed products and development pipeline, visit www.dynavax.com.

Forward-Looking Statements
This press release contains "forward-looking" statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which are subject to a number of risks and uncertainties. All statements that are not historical facts are forward-looking statements. Forward-looking statements can generally be identified by the use of words such as "anticipate," "believe," "continue," "could," "estimate," "expect," "forecast," "intend," "will," "may," "plan," "project," "potential," "seek," "should," "think," "toward," "will," "would" and similar expressions, or the negatives thereof, or they may use future dates. Forward-looking statements made in this document include statements regarding our expected financial results for the year ended December 31, 2024, expectations regarding our future growth and long-term performance, extent and timing of market growth and market share beyond 2030, the timing of IND filings, initiation and completion of clinical studies, expected timing for data readouts, and interaction with regulators. 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 market size or actual demand for our products may differ from our expectations, risks relating to our ability to commercialize and supply HEPLISAV-B, risks related to the timing of completion and results of current clinical studies, risks related to the development and pre-clinical and clinical testing of vaccines containing CpG 1018 adjuvant, as well as other risks detailed in the "Risk Factors" section of our Quarterly Report on Form 10-Q for the three months ended September 30, 2024 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. These forward-looking statements are made as of the date hereof, are qualified in their entirety by this cautionary statement and 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.

Reference herein to any specific commercial products, process, or service by trade name, trademark, manufacturer, or otherwise, does not constitute or imply its endorsement, recommendation, or favoring by the U.S. Government and shall not be used for advertising or product endorsement purposes.

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