# Dynavax Announces Preliminary Unaudited Fourth Quarter and Full Year 2023 Financial Highlights

January 8, 2024 at 9:00 AM EST

- *Preliminary full year 2023 HEPLISAV-B® vaccine net product revenue of approximately $213 million, a 69% year-over-year increase*
- *Significant gains in HEPLISAV-B market share in key market segments, with total U.S. market share increasing to approximately 44% compared to approximately 35% at the end of 2022*
- *Strengthened financial position with cash, cash equivalents and marketable securities at year end increasing to approximately $742 million; expects to be cash flow positive for full year 2024*

EMERYVILLE, Calif., Jan. 8, 2024 /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, 2023.

"In 2023, we delivered a record year of revenue for HEPLISAV-B, driven by the expansion of the adult hepatitis B vaccine market in the U.S., and our team's progress toward establishing HEPLISAV-B as the market leading vaccine. We are extremely pleased with our market share growth in the fourth quarter, which enabled us to achieve our increased product revenue guidance for the year despite the impact of expected seasonality due to increased focus on respiratory disease vaccines during the fall and winter seasons. We believe the seasonal market decline for adult hepatitis B vaccines will be limited to the fourth quarter in line with the administration of the vast majority of influenza and COVID-19 vaccines," said Ryan Spencer, Chief Executive Officer of Dynavax. "Turning to this year, we believe HEPLISAV-B is well-positioned entering 2024, supported by significant market share gains in the total market and in key market segments. We remain extremely confident in the long-term growth of the hepatitis B market, with HEPLISAV-B expected to achieve a majority market share in the U.S. In addition to HEPLISAV-B, we continue to advance our pipeline of innovative vaccine candidates and continue to pursue strategic opportunities to accelerate our growth."

**Preliminary Fourth Quarter and Full Year 2023 Financial and Commercial Highlights**

- Preliminary HEPLISAV-B vaccine net product revenue for the fourth quarter and full year 2023 were approximately $51 million and $213 million, respectively, representing year-over-year growth of approximately 46% and 69% compared to the fourth quarter and full year 2022.
- HEPLISAV-B total market share in the U.S. increased to approximately 44%, compared to approximately 35% at the end of 2022.
- HEPLISAV-B market share in the retail pharmacy segment increased to approximately 60%, compared to approximately 42% at the end of 2022. HEPLISAV-B market share in the Integrated Delivery Networks (IDNs) and Large Clinics segment increased to approximately 58%, compared to approximately 47% at the end of 2022.
- Cash, cash equivalents and marketable securities were approximately $742 million as of December 31, 2023.

*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, 2023. Market share data are preliminary and are as of the latest market data available on December 22, 2023.*

**Expected Commercial and Pipeline 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.*

- Driven by the Centers for Disease Control and Prevention's Advisory Committee of Immunization Practices (ACIP) universal recommendation for adult hepatitis B vaccination, Dynavax continues to expect the adult hepatitis B vaccine market in the U.S. to expand at an annual growth rate of approximately 10 - 15% over the next several years to a total market of approximately $800 million by 2027, one of the largest adult vaccine markets in the U.S., with HEPLISAV-B well-positioned to achieve a majority market share.
- A supplemental Biologic License Application (sBLA) for HEPLISAV-B vaccination of adults on hemodialysis is currently under review by the U.S. Food and Drug Administration (FDA) with a Prescription Drug User Fee Act (PDUFA) action date planned for May 13, 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.*

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

- Dynavax expects to submit an Investigational New Drug Application (IND) to the FDA to support initiation of a Phase 1/2 trial of Z-1018 in the first half of 2024.

**Tdap vaccine program:**
*Tdap-1018 is an investigational vaccine candidate intended for active booster immunization against tetanus, diphtheria, and pertussis (Tdap).*

- Dynavax plans to submit an IND to the FDA to support the initiation of a Phase 2 human challenge study of Tdap-1018 in the second half of 2024, upon completion of the independent study conducted by the Canadian Center for Virology to establish the human challenge dose.

**Plague vaccine program:**
*Dynavax is developing a plague (rF1V) vaccine candidate adjuvanted with CpG 1018® currently in a Phase 2 clinical trial in collaboration with, and fully funded by, the U.S. Department of Defense.*

- Dynavax anticipates top line data for the randomized, active-controlled Phase 2 clinical trial evaluating immunogenicity, safety, and tolerability of the plague vaccine candidate in 2024.

**J.P. Morgan Healthcare Conference Presentation Webcast Details**
Dynavax will present at the 42nd Annual J.P. Morgan Healthcare Conference on Thursday, January 11 at 11:15 a.m. PT.

The presentation will be webcast and may be accessed through the "Events & Presentations" page on the "Investors" section of the Company's website at https://investors.dynavax.com/events-presentations.

**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%).

**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 multiple adjuvanted COVID-19 vaccines. Dynavax is advancing CpG 1018 adjuvant as a premier vaccine adjuvant with adjuvanted vaccine clinical programs for shingles and Tdap, and through global collaborations, currently focused on adjuvanted vaccines for COVID-19, plague, seasonal influenza and universal influenza. 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 and market share as of and for the year and quarter ended December 31, 2023, expectations regarding future growth and market share, and the timing of IND filings, initiation and completion of clinical studies, the publication of results, 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 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 quarter ended September 30, 2023 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.

**For Investors/Media:**
Paul Cox
pcox@dynavax.com
510-665-0499

Nicole Arnd
narndt@dynavax.com
510-665-7264

View original content to download multimedia:https://www.prnewswire.com/news-releases/dynavax-announces-preliminary-unaudited-fourth-quarter-and-full-year-2023-financial-highlights-302027761.html

SOURCE Dynavax Technologies