Dynavax Announces First Quarter 2021 Financial Results

May 6, 2021

- First quarter 2021 total revenue of $83.3 million, driven by strong execution in the CpG 1018 adjuvant business

- Conference call to be held today at 4:30 p.m. ET/1:30 p.m. PT

EMERYVILLE, Calif., May 6, 2021 /PRNewswire/ -- Dynavax Technologies Corporation (Nasdaq: DVAX), a biopharmaceutical company focused on developing and commercializing novel vaccines, today reported financial results for the first quarter of 2021.

"The first quarter of 2021 continued to build on our successful execution in 2020. With the combined strength of opportunities from HEPLISAV-B and CpG 1018, we believe 2021 will be a transformational year for Dynavax," commented Ryan Spencer, Chief Executive Officer of Dynavax. "HEPLISAV-B continues to take market share in accounts targeted by our field sales team, reaching a new high this quarter, which reinforces our belief that it will become the standard of care in the U.S. for adult hepatitis B vaccination."

Mr. Spencer continued, "Dynavax is making progress on numerous collaborations for its proven vaccine adjuvant CpG 1018 across multiple indications, including COVID-19, pertussis, and universal flu. Our COVID-19 collaborations have advanced significantly in recent months with multiple partners targeting emergency or conditional authorization in the second half of 2021. Importantly, these collaborations are now generating significant revenue for Dynavax, with first quarter CpG 1018 revenue of $74.6 million. Additionally, last week we expanded our agreement with CEPI whereby they fund manufacturing of CpG 1018 for future sales to CEPI grantees, providing the opportunity for additional revenue in 2021 from COVID-19 collaborations. The emerging portfolio of product opportunities with CpG 1018 has the potential to drive significant revenue growth beyond this year."

HEPLISAV-B® [Hepatitis B Vaccine (Recombinant), Adjuvanted]

- Net product revenue for HEPLISAV-B during the first quarter 2021 was $8.3 million compared to $10.5 million for the first quarter 2020, driven by increased market share offset by a reduction in vaccine utilization due to the COVID-19 pandemic.
- Market share in accounts targeted by the field sales team increased to 27%, up from 21% market share in the first quarter of 2020.
- Final immunogenicity and interim safety results of the ongoing clinical trial (HBV-24) evaluating HEPLISAV-B in patients undergoing hemodialysis evaluating a new 4-dose regimen of HEPLISAV-B demonstrated a seroprotection rate of 89.3%. Interim safety data showed HEPLISAV-B is well tolerated and no safety concerns were observed. Full safety data are expected by the end of 2021.
- Positive results from the post-marketing observational surveillance study (HBV-25) in over 69,000 patients demonstrated the study met the primary endpoint and showed no evidence of an increased risk of acute myocardial infarction associated with vaccination with HEPLISAV-B compared to Engerix-B.

CpG 1018 (Advanced Vaccine Adjuvant)

- Net product revenue for CpG 1018 during the first quarter 2021 was $74.6 million.
- In February, Dynavax initiated a Phase 1 clinical trial of Tdap-1018, its tetanus, diphtheria, and acellular pertussis (Tdap) booster vaccine product candidate adjuvanted with CpG 1018.
- In March, Clover Biopharmaceuticals dosed the first participant in SPECTRA, a global Phase 2/3 clinical trial for its trimeric SARS-CoV 2 spike (S) protein vaccine adjuvanted with CpG 1018.
- In April, Valneva reported positive initial results for Part A of the Phase 1/2 clinical trial of its VLA2001 COVID-19 vaccine candidate adjuvanted with CpG 1018 and subsequently initiated a pivotal Phase 3 clinical trial.
- In April, Medigen published positive Phase 1 clinical study data demonstrating neutralizing antibody titers 1.8 to 3.9 times that of human convalescent sera for its COVID-19 vaccine candidate adjuvanted with CpG 1018 and has completed enrollment of over 4,000 participants in its on-going Phase 2 clinical trial.
- In April, CEPI expanded its agreement with the Company to provide funding to manufacture CpG 1018 for its COVID-19 vaccine grantees, increasing total funding under the loan agreement from $99 million to $176 million.

2021 Milestones

- Multiple data readouts from our CpG 1018 COVID-19 collaboration partners throughout the year
- Data from the ongoing Phase 1 clinical trial of Tdap-1018 in the fourth quarter
- Launch HEPLISAV-B in the EU in the fourth quarter

Financial Results

Total Revenue. Total revenues for the first quarter of 2021 were $83.3 million, including $82.9 million of net product revenue, an increase from total revenue for the first quarter of 2020 of $10.9 million.

Product Revenue, Net. HEPLISAV-B product revenue, net was $8.3 million in the first quarter of 2021 compared to $10.5 million in the same period in

2020. CpG 1018 product revenue, net was $74.6 million in the first quarter of 2021 compared to $0.0 million in the same period in 2020.

Cost of Sales - Product. Cost of sales - product for the first quarter 2021 increased to $24.6 million, compared to $2.4 million for the first quarter of 2020. The increase was primarily due to manufacturing costs for CpG 1018.

Research and Development Expenses (R&D). R&D expenses for the first quarter of 2021 increased to $7.8 million, compared to $4.7 million for the first quarter of 2020. The increase is primarily due to development activities related to process improvements at our Dusseldorf facility and higher headcount, partially offset by a decrease in business travel due to COVID-19 travel restrictions. In addition, non-cash stock-based compensation in the first quarter of 2020 included reversal of expenses related to cancellation of certain equity grants.

Selling, General and Administrative Expenses (SG&A). SG&A expenses for the first quarter of 2021 increased to $22.4 million, compared to $20.9 million for the first quarter of 2020. Compensation and related personnel costs increased due to higher headcount and an accrual of benefits for a former executive in connection with his retirement, offset by the decrease in business travel due to COVID-19 travel restrictions. Non-cash stock-based compensation increased due to higher headcount.

Income from Operations and Net Income. Income from operations for the first quarter of 2021 was $28.5 million compared to a loss of $19.3 million in the first quarter of 2020. Net income for the first quarter of 2021 was $0.9 million compared to a net loss of $12.6 million for the first quarter of 2020. Basic and diluted net income per share was $0.01 for the first quarter of 2021, compared to a basic net loss of $0.15 per share and diluted net loss per share of $0.25 in the first quarter of 2020.

Cash Position. Cash, cash equivalents and marketable securities totaled $232.7 million at March 31, 2021.

Conference Call and Webcast Information
Dynavax will hold a conference call today at 4:30 p.m. ET/1:30 p.m. PT. The live audio webcast may be accessed through the "Events & Presentations" page on the "Investors" section of the Company's website at www.dynavax.com. Alternatively, participants may dial (866) 420-4066 or (409) 217-8237 and refer to conference ID 4533398. A replay of the webcast will be available for 30 days following the live event.

Please see Important Safety Information below.

For more information about HEPLISAV-B, visit http://heplisavb.com.

About Hepatitis B
Hepatitis B is a viral disease of the liver that can become chronic and lead to cirrhosis, liver cancer and death. The hepatitis B virus is 50 to 100 times more infectious than HIV,[i] and transmission is on the rise. There is no cure for hepatitis B, but effective vaccination can prevent the disease.

In adults, hepatitis B is spread through contact with infected blood and through unprotected sex with an infected person. The U.S. Centers for Disease Control (CDC) recommends vaccination for those at high risk for infection due to their jobs, lifestyle, living situations and travel to certain areas.[ii] Because people with diabetes are particularly vulnerable to infection, the CDC recommends vaccination for adults age 19 to 59 with diabetes as soon as possible after their diagnosis, and for people age 60 and older with diabetes at their physician's discretion.[iii] Approximately 20 million U.S. adults have diabetes, and 1.5 million new cases of diabetes are diagnosed each year.[iv]

About HEPLISAV-B
HEPLISAV-B is an adult hepatitis B vaccine that combines hepatitis B surface antigen with Dynavax's proprietary Toll-like Receptor (TLR) 9 agonist CpG 1018 to enhance the immune response. Dynavax has worldwide commercial rights to HEPLISAV-B.

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

Safety and effectiveness of HEPLISAV-B have not been established in adults on hemodialysis.

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 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%).

Important EU/EEA Product Information
HEPLISAV B is indicated for active immunisation against hepatitis B virus infection (HBV) caused by all known subtypes of hepatitis B virus in adults 18 years of age and older.
The use of HEPLISAV B should be in accordance with official recommendations.
It can be expected that hepatitis D will also be prevented by immunisation with HEPLISAV B as hepatitis D (caused by the delta agent) does not occur in the absence of hepatitis B infection.

For full EU/EEA. Prescribing Information for HEPLISAV-B, click here.

Important EU/EEA Safety information
Do not receive HEPLISAV B if you have had a sudden life-threatening, allergic reaction after receiving HEPLISAV B in the past, or if you are allergic to any of components of this vaccine, including yeast. Signs of an allergic reaction may include itchy skin, rash, shortness of breath and swelling of the face or tongue.
Appropriate medical treatment and supervision should be readily available in case of rare anaphylactic reactions following the administration of the vaccine.

The administration of HEPLISAV B should be postponed in subjects suffering from acute severe febrile illness.
Immunocompromised persons may have a diminished immune response to HEPLISAV B.
Because of the long incubation period of hepatitis B, it is possible for unrecognised HBV infection to be present at the time of immunisation. HEPLISAV B may not prevent HBV infection in such cases.
There are very limited data on the immune response to HEPLISAV B in individuals who did not mount a protective immune response to another hepatitis B vaccine.
As a precautionary measure, it is preferable to avoid the use of HEPLISAV B during pregnancy. Vaccination during pregnancy should only be performed if the risk-benefit ratio at the individual level outweighs possible risks for the fetus.
The most common patient-reported side effects reported within 7 days of vaccination were pain, swelling or redness at the injection site, feeling tired, headache, muscle aches, feeling unwell and fever.

About CpG 1018 Adjuvant
CpG 1018 is the adjuvant used in HEPLISAV-B. Dynavax developed CpG 1018 adjuvant to provide an increased vaccine immune response, which has been demonstrated in HEPLISAV-B. CpG 1018 adjuvant provides a well- developed technology and a significant safety database, potentially accelerating the development and large-scale manufacturing of a COVID-19 vaccine.

About Dynavax
Dynavax is a commercial stage biopharmaceutical company developing and commercializing novel vaccines. 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, pertussis 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 the potential for HEPLISAV-B to become the standard of care adult hepatitis B vaccine in the U.S., establishing CpG 1018 as a leading adjuvant, the development of vaccines containing CpG 1018 and potential future sales of CpG 1018, the timing of initiation and completion of clinical studies and the publication of results, the timing of our collaborators seeking emergency use authorization of COVID-19 vaccines containing CpG 1018 adjuvant, our ability to scale manufacturing capacity, the expected demand for our products, our efforts to develop an improved pertussis vaccine, a vaccine for COVID-19, and a universal flu vaccine, entering into strategic relationships and expected results of such relationships, the potential for CpG 1018 to accelerate development and large scale manufacturing of a COVID-19 vaccine and sales potential under certain agreements. 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 of completion and results of current clinical studies, risks that our collaborators will not get approval of their vaccine candidates, risks related to the development and pre-clinical and clinical testing of vaccines containing CpG 1018, 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 supply CpG 1018 and financial commitments made to them, as well as other risks detailed in the "Risk Factors" section of our Annual Report on Form 10-K for the fiscal year ended December 31, 2020, 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.

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[i] CDC. https://www.cdc.gov/hepatitis/hbv/bfaq.htm.
[ii] CDC. https://www.cdc.gov/hepatitis/hbv/hbvfaq.htm.
[iii] CDC. https://www.cdc.gov/diabetes/pubs/pdf/hepb_vaccination.pdf.
[iv] CDC. https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-r

DYNAVAX TECHNOLOGIES CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except per share amounts)
(Unaudited)

	Three Months Ended March 31,	
	2021	**2020**
Revenues:		
Product revenue, net	$ 82,885	$ 10,514
Other revenue	450	405
Total revenues	83,335	10,919
Operating expenses:		

Cost of sales – product	24,625	2,354
Cost of sales - amortization of intangible assets	-	2,298
Research and development	7,758	4,653
Selling, general and administrative	22,423	20,926
Total operating expenses	54,806	30,231
Income (loss) from operations	28,529	(19,312)
Other income (expense):		
Interest income	47	590
Interest expense	(4,712)	(4,731)
Sublease income	2,022	1,926
Change in fair value of warrant liability	(25,552)	8,610
Other	557	322
Net income (loss)	**$ 891**	**$ (12,595)**
Basic net income (loss) per share	**$ 0.01**	**$ (0.15)**
Weighted average shares used to compute basic net income (loss) per share	**112,035**	**85,477**
Diluted net income (loss) per share	**$ 0.01**	**$ (0.25)**
Weighted average shares used to compute diluted net income (loss) per share	**113,469**	**85,648**

DYNAVAX TECHNOLOGIES CORPORATION
SELECTED BALANCE SHEET DATA
(In thousands)
(Unaudited)

	March 31, 2021	December 31, 2020
Assets		
Cash, cash equivalents and marketable securities	$ 232,674	$ 165,036
Inventories, net	68,846	63,689
Property and equipment, net	30,696	30,567
Operating lease right-of-use assets	25,799	26,583
Goodwill	2,197	2,297
Other assets	129,907	65,100
Total assets	**$ 490,119**	**$ 353,272**
Liabilities and stockholders' equity		
Total current liabilities	$ 109,422	$ 77,411
Total long-term liabilities	280,935	217,168
Stockholders' equity	99,762	58,693
Total liabilities and stockholders' equity	**$ 490,119**	**$ 353,272**

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