Dynavax Announces Fourth Quarter and Full Year 2020 Financial Results

February 25, 2021

-- Substantial progress in 2020 on both HEPLISAV-B and CpG 1018 businesses
-- Full year 2020 total revenue of $46.6 million, an increase of 32% from 2019 total revenue of $35.2 million
-- First quarter 2021 CpG 1018 revenue anticipated to be between $40 million and $60 million
-- Conference call to be held today at 4:30 p.m. ET/1:30 p.m. PT

EMERYVILLE, Calif., Feb. 25, 2021 /PRNewswire/ -- Dynavax Technologies Corporation (Nasdaq: DVAX), a biopharmaceutical company focused on developing and commercializing novel vaccines, today reported financial results for the fourth quarter and full year 2020.

"2020 was an important year for Dynavax as we continue to build a leading vaccine company underpinned by growing recurring revenue from both HEPLISAV-B and CpG 1018," commented Ryan Spencer, Chief Executive Officer of Dynavax. "In addition to HEPLISAV-B, we continue to progress numerous collaborations to develop our proven vaccine adjuvant CpG 1018 across multiple indications, including COVID–19, pertussis, and universal flu."

Mr. Spencer added, "Our COVID-19 collaborations have advanced significantly in recent months with multiple partners targeting emergency use authorization in the second half of 2021. The emerging portfolio of product opportunities with CpG 1018 has the potential to drive significant revenue growth in 2021 and beyond. Through the continued advancement of our multiple collaborations, CpG 1018 could be utilized in up to 500 million to 1.5 billion doses of vaccine annually starting in 2022, with additional capacity expansion available depending on global demand."

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

- Full year 2020 net product revenue of $36.0 million compared to $34.6 million for full year 2019, a 4% year-over-year growth rate despite the substantial ongoing reduction in market utilization due to the pandemic and COVID-19 vaccine rollout.
- Net product revenue for HEPLISAV-B during the fourth quarter 2020 was $11.5 million, up 8.5% year-over-year from $10.6 million for the fourth quarter of 2019.
- Market share in accounts targeted by the field sales team increased to 26%, up from 20% market share in the fourth quarter of 2019.
- Received Marketing Authorization in February 2021 from the European Commission following the positive opinion in December 2020 from the European Medicines Agency (EMA) Committee for Medicinal Products for Human Use (CHMP).
- Reported final immunogenicity data from a study in adults with end-stage renal disease (ESRD) undergoing hemodialysis. In this study of 119 patients, HEPLISAV-B demonstrated a high seroprotection rate of 89.3% at week 20 after 4 standard doses.

CpG 1018 (Advanced Vaccine Adjuvant)

- Dynavax is scheduled to supply CpG 1018 to produce up to 100 million doses of Valneva's SE adjuvanted COVID-19 vaccine in 2021, which would generate CpG 1018 revenue of up to $230 million in 2021, contingent on the continued success of Valneva's vaccine candidate.
- First quarter 2021 CpG revenue is anticipated to be between $40 million and $60 million.
- Clover Biopharmaceuticals is initiating a global Phase 2/3 efficacy trial with their protein sub–unit COVID-19 vaccine candidate adjuvanted with CpG 1018 with an interim analysis for vaccine efficacy expected in the middle of 2021.
- Coalition for Epidemic Preparedness Innovations (CEPI) agreed to provide funding of up to $99 million for advanced manufacturing of CpG 1018 for use in COVID–19 vaccines developed by CEPI grantees to ensure product availability in 2021 upon emergency use authorization.
- Dynavax dosed the first participant in a Phase 1 clinical trial evaluating a tetanus, diphtheria, and acellular pertussis (Tdap) booster vaccine candidate adjuvanted with CpG 1018.

Additional Corporate Updates

- Appointed Kelly MacDonald as Senior Vice President and Chief Financial Officer
- Dong Yu, Ph.D., joined as Senior Vice President of Vaccine Research

2021 Milestones

- Publication of data from the study of HEPLISAV-B in patients on hemodialysis anticipated in the first half
- Multiple data readouts from our CpG 1018 collaboration partners throughout the year
- Final report for HEPLISAV-B post-marketing study expected in the second quarter

- Data from the ongoing Phase 1 study of an improved Tdap vaccine candidate adjuvanted with CpG 1018 anticipated in the fourth quarter
- Launch HEPLISAV-B in the EU in the fourth quarter

Financial Results

Total Revenues and Product Revenue, Net. Total revenues for the fourth quarter of 2020 were $19.6 million, including $13.1 million of net product revenue. Total revenues for 2020 were $46.6 million compared to $35.2 million for 2019. HEPLISAV-B product revenue, net increased to $11.5 million in the fourth quarter of 2020 compared to $10.6 million in the same period in 2019. Full year product revenue, net for HEPLISAV-B in 2020 was $36.0 million compared to $34.6 million for the full year 2019. CpG 1018 product revenue, net was $1.6 million in the fourth quarter of 2020 compared to $0.0 million in the same period in 2019. Full year product revenue, net for CpG 1018 in 2020 was $3.3 million compared to $0.0 million for the full year 2019.

Cost of Sales - Product. Cost of sales - product for the fourth quarter 2020 increased to $4.1 million, compared to $2.4 million for the fourth quarter of 2019. Full year 2020 cost of sales - product was $11.4 million compared to $10.2 million for the full year 2019. The increase was primarily due to higher unit costs for HEPLISAV-B as we produce and then sell inventory that reflects the full cost of manufacturing. For the six months ended December 31, 2020, cost of sales-product included $1.4 million of costs to produce CpG 1018 for our collaboration partners. The Company anticipates cost of sales - product to increase substantially in 2021 due to increased manufacturing of CpG 1018 under the supply agreement with Valneva.

Research and Development Expenses. Research and development (R&D) expenses for the fourth quarter of 2020 decreased to $9.5 million, compared to $12.3 million for the fourth quarter of 2019. Full year 2020 R&D expenses were $28.6 million compared to $62.3 million for the full year 2019. The decrease in R&D expenses is due to personnel costs, facilities overhead cost allocations and non-cash stock-based compensation decreases due to lower R&D headcount resulting from our restructuring in May 2019 and the winding down of our immuno-oncology programs and an increase of additional CpG 1018 development costs at our third-party manufacturing facility to support increased CpG 1018 demand from our collaboration partners for use in their development and/or commercialization of COVID-19 vaccines.

SG&A Expenses. Selling, general and administrative (SG&A) expenses for the fourth quarter of 2020 decreased to $17.8 million, compared to $20.3 million for the fourth quarter of 2019. Full year 2020 SG&A expenses were $79.3 million compared to $75.0 million for the full year 2019.

Loss from Operations and Net Income Loss. Loss from operations for the fourth quarter of 2020 decreased to $11.9 million from $27.4 million in the fourth quarter of 2019. Full year 2020 loss from operations decreased to $68.4 million compared to $134.8 million for the full year 2019. Net loss for the fourth quarter of 2020 was $15.5 million compared to a net loss of $36.8 million for the fourth quarter of 2019. Basic and diluted net loss per share was $0.14 for the fourth quarter of 2020, compared to $0.44 per basic and diluted net loss per share in the fourth quarter of 2019. Full year 2020 net loss decreased to $75.2 million or $0.75 per basic and $0.78 per diluted share compared to $152.6 million or $2.16 per basic and diluted share for the full year 2019.

Cash Position. Cash, cash equivalents and marketable securities totaled $165.0 million at December 31, 2020.

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 8380559. 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.

Indication and Use

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

Important 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%).

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

About CpG 1018

CpG 1018 is the adjuvant used in HEPLISAV-B® [Hepatitis B Vaccine (Recombinant), Adjuvanted], an adult hepatitis B vaccine approved by the U.S. Food and Drug Administration (FDA). Dynavax developed CpG 1018 to provide an increased vaccine immune response, which has been demonstrated in HEPLISAV-B. CpG 1018 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. 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 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, expected revenue for the first fiscal quarter of 2021, expected full-year revenue from Valneva, the launch of HEPLISAV-B in Europe, 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, 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, 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 of HEPLISAV-B, 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, and risks related to the launch of HEPLISAV B in Europe, 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 December 31,		Twelve Months Ended December 31,	
	2020	**2019**	**2020**	**2019**
Revenues:				
Product revenues, net	$ 13,112	$ 10,558	$ 39,307	$ 34,644
Other revenue	6,438	12	7,244	575
Total revenues	**19,550**	**10,570**	**46,551**	**35,219**
Operating expenses:				
Cost of sales - product	4,058	2,407	11,410	10,172
Cost of sales - amortization of intangible assets	-	2,323	2,500	9,217
Research and development	9,549	12,269	28,607	62,331
Selling, general and administrative	17,838	20,318	79,256	74,986

Gain on sale of assets	-	-	(6,851)	-
Restructuring	-	642	-	13,356
Total operating expenses	**31,445**	**37,959**	**114,922**	**170,062**
Loss from operations	(11,895)	(27,389)	(68,371)	(134,843)
Other income (expense):				
Interest income	70	766	1,260	3,370
Interest expense	(4,805)	(4,866)	(19,062)	(16,977)
Sublease income	1,927	1,728	7,706	2,619
Change in fair value of warrant liability	(76)	(7,266)	4,124	(7,500)
Other	(688)	271	(897)	731
Net loss	**$ (15,467)**	**$ (36,756)**	**$ (75,240)**	**$ (152,600)**
Preferred stock deemed dividend	-	-	-	(3,267)
Net loss allocable to common stockholders	$ (15,467)	$ (36,756)	$ (75,240)	$ (155,867)
Basic net loss per share allocable to common stockholders	**$ (0.14)**	**$ (0.44)**	**$ (0.75)**	**$ (2.16)**
Weighted average shares used to compute basic net loss per share allocable to common stockholders	110,176	83,868	100,753	72,024
Diluted net loss per share allocable to common stockholders	**$ (0.14)**	**$ (0.44)**	**$ (0.78)**	**$ (2.16)**
Weighted average shares used to compute diluted net loss per share allocable to common stockholders	110,176	83,868	101,504	72,024

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

	December 31, 2020	December 31, 2019
Assets		
Cash, cash equivalents and marketable securities	$ 165,036	$ 151,055
Inventories, net	63,689	41,332
Property and equipment, net	30,567	32,022
Intangible assets, net	-	2,500
Operating lease right-of-use assets	26,583	30,252
Goodwill	2,297	2,081
Other assets	65,100	19,826
Total assets	**$ 353,272**	**$ 279,068**
Liabilities and stockholders' equity		
Total current liabilities	$ 77,411	$ 53,047
Total long-term liabilities	217,168	217,731
Stockholders' equity	58,693	8,290
Total liabilities and stockholders' equity	**$ 353,272**	**$ 279,068**

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