Dynavax Announces Fourth Quarter and Full Year 2019 Financial Results

March 11, 2020

- Full year 2019 HEPLISAV-B® net product revenue of $34.6 million, in line with upwardly-revised guidance
- Aim to grow 2020 HEPLISAV-B® net product revenue by approximately 70 percent over 2019
- Advancing efforts to leverage Dynavax's vaccine adjuvant CpG 1018 in product candidates for pertussis and coronavirus (COVID-19)
- Conference call to be held today at 4:30 p.m. ET/1:30 p.m. PT

EMERYVILLE, Calif., March 11, 2020 (GLOBE NEWSWIRE) -- 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 2019.

"Vaccines offer an unmatched value to the healthcare system and Dynavax continues to make tremendous progress on its transformation into a leading vaccine company. Our first product, HEPLISAV-B, provides adults higher and faster protection from hepatitis B in just two doses compared to previously available vaccines," commented Ryan Spencer, Chief Executive Officer of Dynavax. "We are excited by the response from our customers and our continued success in growing market share, which reinforces our belief that HEPLISAV-B has the potential to become the standard of care for adult hepatitis B vaccination in the U.S."

Mr. Spencer added, "Our focus in 2020 is driving annual revenue growth of HEPLISAV-B, generating data to support a unique dosing regimen for patients on hemodialysis, and supporting policy initiatives aimed at protecting more adults through adoption of a two-dose regimen, all of which position HEPLISAV-B for substantial long-term growth."

2019 Results and Recent Business Highlights

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

- Full year 2019 net product revenue of $34.6 million compared to $6.8 million for 2018.
- Market share in accounts targeted by the field sales team increased to 21% in the fourth quarter 2019 from 18% in the third quarter 2019.
- The Company filed the cumulative analysis (comprising both required interim analyses) of its post-marketing study assessing the rates of occurrence of acute myocardial infarction in persons receiving HEPLISAV-B compared with Engerix-B with the U.S. Food and Drug Administration. The event rates were similar between the two treatment arms.
- Announced partnership with Albertsons Companies' 1,700 pharmacies nationwide, to provide HEPLISAV-B to people living with diabetes.

Corporate Updates

- Established research collaboration with the University of Queensland and the Coalition for Epidemic Preparedness to develop a coronavirus (COVID-19) vaccine.
- Appointed Ryan Spencer Chief Executive Officer and to the Board of Directors.
- Appointed David Novack President and Chief Operating Officer.

2020 Milestones

- HEPLISAV-B® net product revenue expected to increase to $55-$62 million for the full year 2020
- Release interim data from ongoing study of HEPLISAV-B in patients on hemodialysis in Q1 2020 and final immunogenicity data in the second half of 2020
- Complete Phase 1-enabling animal studies and toxicology for improved pertussis vaccine with CpG 1018
- Enter multiple strategic relationships focused on initial research in a variety of vaccine candidates to establish CpG 1018 as a leading adjuvant
- Complete safety follow-up for HEPLISAV-B post-marketing studies in Q4 2020

Financial Results

Product Revenue, Net. HEPLISAV-B was launched in the first quarter of 2018. Net product revenue for the fourth quarter 2019 was $10.6 million, compared to $3.9 million for the fourth quarter 2018. Full year net product revenue for 2019 was $34.6 million compared to $6.8 million for the full year 2018. Product revenue from sales is recorded at the net sales price, which includes estimates of product returns, chargebacks, discounts and other fees.

Cost of Sales - Product. Cost of sales - product for the fourth quarter 2019 was $2.4 million, compared to $1.6 million for the fourth quarter 2018. Full year 2019 cost of sales - product was $10.2 million, compared to $10.9 million for the full year 2018.

R&D Expenses. Research and development (R&D) expenses for the fourth quarter of 2019 were $12.3 million, compared to $22.9 million for the

fourth quarter of 2018. Full year 2019 R&D expenses were $62.3 million, compared to $75.0 million for the full year 2018. The decrease in R&D expenses is due to the winding down of oncology research and development activity resulting from the Company's strategic organizational restructuring to focus on its vaccine business that was implemented in May 2019. R&D expenses in the fourth quarter of 2019 included approximately $3 million in external expenses related to oncology programs. These expenses are expected to continue to decrease over the next three quarters as activities are completed, with total additional external expenses over that period anticipated to be approximately $6 million.

SG&A Expenses. Selling, general and administrative (SG&A) expenses for the fourth quarter of 2019 were $20.3 million, compared to $16.4 million for the fourth quarter of 2018. Full year 2019 SG&A expenses were $75.0 million, compared to $64.8 million for the full year 2018. The increase for both the three and 12 months ended December 31, 2019 compared to 2018, was due primarily to increases in sales and marketing activities, payments for completion of certain milestones in the HEPLISAV-B post-marketing study and higher facility costs due to an increase in facility related overhead allocation to SG&A functions following the May restructuring and increased lease expense which is being recouped through a sublease to a third party and recorded as part of other income (expense).

Net Loss. Net loss allocable to common stockholders for the fourth quarter of 2019 was $36.8 million, or $0.44 per basic and diluted share, compared to a net loss of $40.0 million, or $0.64 per basic and diluted share, for the fourth quarter of 2018. Full year, net loss allocable to common stockholders, was $155.9 million, or $2.16 per basic and diluted share, compared to a net loss of $158.9 million, or $2.55 per basic and diluted share for the full year 2018.

Cash Position. Cash, cash equivalents and marketable securities totaled $151.1 million at December 31, 2019.

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 800-458-4121 (domestic) or 720-543-0206 (international) and refer to conference ID 1989638. A replay of the webcast will be available for 30 days following the live event.

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 to enhance the immune response. Dynavax has worldwide commercial rights to HEPLISAV-B.

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

About Dynavax
Dynavax is a commercial stage biopharmaceutical company developing and commercializing novel vaccines. The Company launched its first commercial product, HEPLISAV-B® [Hepatitis B Vaccine (Recombinant), Adjuvanted], in February 2018, following U.S. FDA approval for prevention of infection caused by all known subtypes of hepatitis B virus in adults age 18 years and older. 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., revenue projections for HEPLISAV-B, long-term growth of HEPLISAV-B, the timing of enrollment in and completion of clinical studies, the results of clinical studies and what the results will demonstrate or support, developing an improved pertussis vaccine and other vaccines, entering into strategic relationships, establishing CpG 1018 as a leading adjuvant, and revenue and expense expectations for 2020. 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 the vaccine market and/or the adult hepatitis B market may not grow as expected, the risk that HEPLISAV-B may not provide the anticipated benefits and may not become the standard of care adult hepatitis B vaccine in the U.S., the risk that our growth initiatives may not be successful, the risk that our 2020 revenue and/or expenses may not meet our expectations, 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 and the adverse effects of the recent coronavirus pandemic on our ability to access customers and on customer decision making, adoption and implementation; as well as other risks detailed in the "Risk Factors" section of our Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2019, 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-report.pdf.

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

	Three Months Ended December 31,		Year Ended December 31,	
	2019	**2018**	**2019**	**2018**
Revenues:				
Product revenues, net	$ 10,558	$ 3,932	$ 34,644	$ 6,812
Collaboration revenue	-	1,386	143	1,386
Other revenue	12	-	432	-
Total revenues	**10,570**	**5,318**	**35,219**	**8,198**
Operating expenses:				
Cost of sales – product	2,407	1,625	10,172	10,934
Cost of sales - amortization of intangible assets	2,323	2,324	9,217	10,862
Research and development	12,269	22,892	62,331	74,951
Selling, general and administrative	20,318	16,438	74,986	64,770
Restructuring	642	-	13,356	-
Total operating expenses	**37,959**	**43,279**	**170,062**	**161,517**
Loss from operations	(27,389)	(37,961)	(134,843)	(153,319)
Other income (expense):				
Interest income	766	888	3,370	3,828
Interest expense	(4,866)	(2,751)	(16,977)	(9,338)
Sublease income	1,728	-	2,619	-
Change in fair value of warrant liability	(7,266)	-	(7,500)	-
Other income (expense), net	271	(145)	731	(70)
Net loss	(36,756)	(39,969)	(152,600)	(158,899)
Preferred stock deemed dividend	-	-	(3,267)	-
Net loss allocable to common stockholders	**$ (36,756)**	**$ (39,969)**	**$ (155,867)**	**$ (158,899)**
Net loss per share allocable to common stockholders – basic and diluted	**$ (0.44)**	**$ (0.64)**	**$ (2.16)**	**$ (2.55)**
Weighted average shares used to compute basic and diluted net loss per share allocable to common stockholders	**83,868**	**62,694**	**72,024**	**62,362**

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

	December 31, 2019	December 31, 2018
Assets		
Cash, cash equivalents and marketable securities	$ 151,055	$ 145,536
Inventories, net	41,332	19,022
Property and equipment, net	32,022	17,064
Intangible assets, net	2,500	11,717
Goodwill	2,081	2,144
Other assets	50,078	15,401
Total assets	**$ 279,068**	**$ 210,884**
Liabilities and stockholders' equity		
Total current liabilities	$ 53,047	$ 38,033
Total long-term liabilities	217,731	109,786

Stockholders' equity	8,290	63,065
Total liabilities and stockholders' equity	**$ 279,068**	**$ 210,884**

Source: Dynavax Technologies Corporation