Dynavax Announces Fourth Quarter and Full Year 2018 Financial Results

February 26, 2019

- Fourth quarter 2018 HEPLISAV-B® net product revenue of $3.9 million
- Phase Ib/2 safety data for inhaled DV281 will be presented at the AACR Annual Meeting
- SD-101 demonstrates consistent and meaningful clinical benefit to anti-PD-1 therapy
- Conference call to be held today at 4:30 p.m. ET/1:30 p.m. PT

BERKELEY, Calif., Feb. 26, 2019 (GLOBE NEWSWIRE) -- Dynavax Technologies Corporation (NASDAQ: DVAX), a fully-integrated biopharmaceutical company focused on discovering and developing novel vaccines and immuno-oncology therapeutics, today reported financial results for the fourth quarter and year ended December 31, 2018.

“I am proud of our 2018 achievements, particularly the launch of HEPLISAV-B, which enabled us to generate revenue of $3.9 million in the fourth quarter,” said Eddie Gray, chief executive officer of Dynavax. “HEPLISAV-B is the only two-dose hepatitis B vaccine, and it consistently protects more than 90% of adult patients. We are confident that it is poised to become the standard of care hepatitis B adult vaccine, and remain firm in our expectation that HEPLISAV-B operations will become profitable by the end of 2019.”

Mr. Gray continued. “In immuno-oncology, we are focused on paths to approval where we believe our TLR9 technology has a competitive advantage. SD-101, in combination with pembrolizumab has consistently demonstrated response rates in melanoma and head and neck cancer that are higher than those reported for pembrolizumab alone. We are actively evaluating a number of opportunities, including partnerships, to advance SD-101 into registrational studies, and are committed to being thoughtful and diligent in determining the best path forward to drive value for our shareholders and provide better options for patients.”

2018 and Recent Business Highlights

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

- Fourth quarter 2018 sales of $3.9 million compared to $1.5 million in the third quarter 2018
- More than 1,200 individual customers purchased HEPLISAV-B in 2018
- More than 80% of doses sold to date were purchased by repeat customers
- 592 of the largest targeted customers, which represent more than 36% of the targeted doses, have received P&T committee approval; 354 have progressed to purchase
- Purchase contracts have been executed with 3 of the top 10 retail pharmacies
- Initial purchases by state and county health departments through the CDC Vaccines for Adults program began in the first quarter of 2019

Immuno-oncology

SD-101

SD-101 adds meaningful clinical benefit to KEYTRUDA® (pembrolizumab) therapy.

- In November, the company presented encouraging and consistent results from the Phase 1b/2 trial of SD-101 in combination with KEYTRUDA® at the ESMO 2018 Congress:

  - In patients with advanced melanoma who are naïve to anti-PD-1 therapy
    - 70% overall response rate (ORR) in the 2-milligram dose cohort
    - Tumor shrinkage occurred in both injected target lesions and non-injected target lesions; non-injected lesions demonstrated an ORR of 68%, including visceral metastases in the lung and liver
    - The ORR is identical to that reported at ASCO 2018, despite increasing the patient population by more than 50%, from 30 to 47 patients
    - 85% 6-month progression-free survival (PFS) rate
    - Observed responses in injected lesions and non-injected distant lesions
    - Responses were independent of baseline PD-L1 expression

  - In patients with melanoma refractory or resistant to anti-PD-1 therapy
    - 20.7% ORR in 29 patients in the 8-milligram dose cohort

  - In patients with head and neck squamous cell carcinoma who were naïve to anti-PD-1 therapy
    - 27.3% ORR in 22 patients in the 8-milligram dose cohort

- Dynavax has fully enrolled the 2-milligram cohort in patients with melanoma refractory or resistant to anti-PD-1 therapy and in patients with head and neck squamous cell carcinoma who were naïve to anti-PD-1 therapy. Data from these cohorts are expected later this year.

- SD-101 and KEYTRUDA® are being evaluated in a new randomized, controlled, investigational treatment arm for the ongoing I-SPY 2 TRIAL™ for neoadjuvant treatment of locally advanced breast cancer.

- Adverse events related to SD-101 treatment have been transient, mild to moderate flu-like symptoms.

DV281

DV281 is a TLR9 agonist designed for delivery to lung cancer patients by inhalation.

- Dynavax is conducting a Phase 1b/2 clinical trial in subjects with advanced non-small cell lung cancer to investigate the safety and tolerability of DV281 as monotherapy and in combination with OPDIVO® (nivolumab) and to identify a recommended dose for the expansion part of the study.

- Studies in preclinical animal models of metastatic cancer show that direct delivery of DV281 to tumor-bearing lungs results in induction of interferons and cytokines and infiltration of T cells, responses similar to those observed after intratumoral injection of SD-101.

- Dynavax will present a poster (Abstract 8304) from the safety portion of the inhaled DV281 study at the AACR Annual Meeting. The poster titled "Phase Ib/II, open label, multicenter study of inhaled DV281, a Toll-like receptor 9 agonist, in combination with nivolumab in patients with advanced or metastatic non small cell lung cancer (NSCLC)" will be presented Tuesday, April 2, 2019, from 1 to 5 p.m. ET.

Preclinical Research
Dynavax has multiple immuno-oncology preclinical research programs including a cancer vaccine program and a multi-pronged program to develop TLR7 and TLR8 agonists, both as anti-cancer agents and as vaccine adjuvants. The company is also evaluating additional candidates to leverage the hepatitis B 1018 adjuvant in additional vaccines.

Financial Results

Product Revenue, Net. Dynavax's first commercial product, HEPLISAV-B, was launched in the first quarter of 2018. Net product revenue for the fourth quarter of 2018 was $3.9 million, compared to $1.5 million in the third quarter of 2018. Net product revenue for the full year 2018 was $6.8 million. 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 of 2018 was $1.6 million and $10.9 million for the year ended December 31, 2018. Included in cost of sales, product, are inventory reserves and fill, finish and overhead costs for HEPLISAV-B incurred after FDA approval. Also included are costs associated with resuming operations at the manufacturing facility in Düsseldorf after receiving regulatory approval for the pre-filled syringe presentation, which costs previously were included in research and development expense.

R&D Expenses. Research and development expenses for the fourth quarter of 2018 totaled $22.9 million compared to $17.4 for the fourth quarter 2017. Full year 2018 research and development expenses totaled $75.0 million compared to $65.0 million in 2017. The increase reflects increased compensation and related personnel costs and clinical trial and research expenses related to the ongoing development of SD-101, DV281 and earlier stage oncology programs. Upon approval of pre-filled syringes in the first quarter 2018, costs associated with resuming activities at the manufacturing facility in Düsseldorf were charged to cost of sales, product while costs incurred to manufacture HEPLISAV-B for commercial sale were accounted for as inventory.

SG&A. Selling, general and administrative expenses for the fourth quarter of 2018 totaled $16.4 million compared to $9.3 million for the fourth quarter of 2017. Full year 2018 selling, general and administrative expenses totaled $64.8 million compared to $27.4 million in 2017. The increase in full year 2018 is primarily due to an overall increase in HEPLISAV-B sales, marketing and commercial activities, including full-deployment of a contract sales force, post-marketing studies and consultants for commercial development services.

Net Loss. Net loss for the fourth quarter of 2018 was $40.0 million, or $0.64 per basic and diluted share, compared to a net loss of $27.4 million, or $0.45 per basic and diluted share, for the fourth quarter of 2017. Full year 2018 net loss was $158.9 million, or $2.55 per basic and diluted share, compared to a net loss of $95.2 million, or $1.81 per basic and diluted share for the full year 2017.

Cash Position. Cash, cash equivalents and marketable securities totaled $145.5 million at December 31, 2018, compared to $191.9 million at December 31, 2017. Dynavax plans to borrow $75.0 million under its non-dilutive term loan agreement in the first quarter of 2019 to support commercial efforts and advance its immuno-oncology platform.

Conference Call and Webcast Information

Dynavax will hold a conference call today at 4:30 p.m. ET/1:30 p.m. PT. To access the call, participants must dial (877) 423-9813 in the U.S. or (201) 689-8573 internationally, and use the conference ID 13687416. The live call will be webcast and can be accessed in the "Investors and Media" section of the company's website at www.dynavax.com. 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. In 2015, new cases of acute hepatitis B increased by more than 20 percent nationally.[ii] 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 CDC recommends vaccination for those at high risk for infection due to their jobs, lifestyle, living situations and travel to certain areas.[iii] 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.[iv] Approximately 20 million U.S. adults have diabetes, and 1.5 million new cases of diabetes are diagnosed each year.[v]

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 SD-101
SD-101, the Company's lead clinical candidate, is a proprietary, second-generation, Toll-like receptor 9 (TLR9) agonist CpG-C class oligodeoxynucleotide. Dynavax is evaluating this intratumoral TLR9 agonist in several clinical studies to assess its safety and activity, including a Phase 1b/2 study in combination with KEYTRUDA® (pembrolizumab), an anti-PD-1 therapy, in patients with advanced melanoma and in patients with head and neck squamous cell cancer, in a clinical collaboration with Merck. Dynavax maintains all commercial rights to SD-101.

About Dynavax
Dynavax is a fully-integrated biopharmaceutical company focused on leveraging the power of the body's innate and adaptive immune responses through toll-like receptor (TLR) stimulation. Dynavax discovers and develops novel vaccines and immuno-oncology therapeutics. 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. Dynavax's lead immunotherapy product, SD-101, is an investigational cancer immunotherapeutic currently being evaluated in Phase 1/2 studies and its second cancer immunotherapeutic, DV281, is in Phase 1 development. For more information, visit www.dynavax.com.

Forward-Looking Statements
This press release contains "forward-looking" statements, including statements regarding the commercialization of HEPLISAV-B, conduct of clinical trials of SD-101, including results from the Phase 1b/2 trial and potential value of SD-101 across multiple tumor types, conduct of clinical trials of DV281, and a planned borrowing under its existing term loan agreement. Actual results may differ materially from those set forth in this press release due to the risks and uncertainties inherent in our business, including whether we are able to continue to build the commercial infrastructure required to increase adoption of HEPLISAV-B; whether payers will provide timely reimbursement for HEPLISAV-B; whether prescribers and other key decision-makers will switch to HEPLISAV-B; whether we can timely provide adequate clinical supplies; initiation, enrollment and completion of clinical trials of SD-101 and DV281; the results of clinical trials and the impact of those results on the initiation or continuation of subsequent trials and issues arising in the regulatory process; the ability to successfully develop and commercialize SD-101 and DV281; and whether or not Dynavax and parties with whom we are collaborating, or other parties, may reach any future agreement on further studies or a more extensive collaboration beyond the clinical trials contemplated under the existing agreements, 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, 2017 and in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2018, 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.

KEYTRUDA is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.

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[i] CDC. https://www.cdc.gov/hepatitis/hbv/bfaq.htm.
[ii] CDC. https://www.cdc.gov/hepatitis/statistics/2015surveillance/index.htm#tabs-5-8. Fig 3.2
[iii] CDC. https://www.cdc.gov/hepatitis/hbv/hbvfaq.htm.
[iv] CDC. https://www.cdc.gov/diabetes/pubs/pdf/hepb_vaccination.pdf.
[v] 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,		Years Ended December 31,	
	2018	**2017**	**2018**	**2017**
Revenues:				
Product revenue, net	$ 3,932	$ -	$ 6,812	$ -
Collaboration revenue	1,386	-	1,386	-
Other revenues	-	21	-	327
Total revenues	**5,318**	**21**	**8,198**	**327**
Operating expenses:				
Cost of sales - product	1,625	-	10,934	-

Cost of sales - amortization of intangible assets	2,324	1,194	10,862	1,194
Research and development	22,892	17,412	74,951	64,988
Selling, general and administrative	16,438	9,256	64,770	27,367
Restructuring	-	-	-	2,783
Total operating expenses	**43,279**	**27,862**	**161,517**	**96,332**
Loss from operations	(37,961)	(27,841)	(153,319)	(96,005)
Other income (expense):				
Interest income	888	528	3,828	1,337
Interest expense	(2,751)	-	(9,338)	-
Other expense, net	(145)	(108)	(70)	(486)
Net loss	**$ (39,969)**	**$ (27,421)**	**$ (158,899)**	**$ (95,154)**
Basic and diluted net loss per share	**$ (0.64)**	**$ (0.45)**	**$ (2.55)**	**$ (1.81)**
Weighted average shares used to compute basic and diluted net loss per share	**62,694**	**61,007**	**62,362**	**52,613**

DYNAVAX TECHNOLOGIES CORPORATION

SELECTED BALANCE SHEET DATA

(In thousands)

(Unaudited)

	December 31, 2018	**December 31, 2017**
Assets		
Cash, cash equivalents and marketable securities	$ 145,536	$ 191,854
Inventories, net	19,022	312
Property and equipment, net	17,064	16,619
Intangible assets, net	11,717	1,306
Goodwill	2,144	2,244
Other assets	15,401	6,450
Total assets	**$ 210,884**	**$ 218,785**
Liabilities and stockholders' equity		
Total current liabilities	$ 38,033	$ 18,593
Total long-term liabilities	109,786	643
Stockholders' equity	63,065	199,549
Total liabilities and stockholders' equity	**$ 210,884**	**$ 218,785**

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Source: Dynavax Technologies Corporation