Dynavax Reports Third Quarter 2018 Financial Results, Progress on HEPLISAV-B Launch, and Updated SD-101 Data in Three Patient Populations

November 5, 2018

Conference Call to be held Today at 4:30pm ET/1:30pm PT

BERKELEY, Calif., Nov. 05, 2018 (GLOBE NEWSWIRE) -- Dynavax Technologies Corporation (NASDAQ: DVAX) today reported financial results for the third quarter ended September 30, 2018 along with an update on the launch progress of HEPLISAV-B and an overview of recently presented data for SD-101 in combination with KEYTRUDA®.

Recent Highlights

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

- P&T approval in six of the top ten integrated delivery networks
- 402 of the largest targeted customers have received P&T committee approval, of whom 200 have progressed to purchase and 68 have implemented HEPLISAV-B throughout their system
- Another 291 target customers have sub-committee or P&T committee reviews scheduled
- Q3 sales of $1.5 million compared to $1.2 million in Q2

Immuno-oncology

Encouraging results for SD-101 Phase 1b/2 data in combination with KEYTRUDA® presented at the ESMO 2018 Congress:

- In 47 advanced melanoma patients naïve to anti PD-1 therapy who received 2mg dose:
  -- Overall response rate (ORR) of 70%, identical ORR to previous report at ASCO with a greater than 50 percent increase in number of patients
  -- 85% 6-month progression-free survival (PFS) rate
  -- Observed responses in injected lesion(s) and non-injected distant lesions, including visceral metastases in the liver and lung
  -- Responses were independent of baseline PD-L1 expression
  -- Adverse events related to SD-101 treatment were transient, mild to moderate flu-like symptoms
- 21.4 percent ORR in 29 melanoma patients refractory or resistant to anti-PD-1 therapy who received the 8 mg dose
- 27.3% ORR in 22 patients with head and neck squamous cell carcinoma who were naïve to anti-PD-1 and received the 8 mg dose
- End-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA) completed

“We achieved multiple objectives over the past few months in both the HEPLISAV-B commercial program and the SD-101 clinical program. Our HEPLISAV-B results in September and particularly October, together with our projections for November and December give us confidence we are now experiencing the start of the inflection in HEPLISAV-B sales we consistently have anticipated for year end. We remain firm in our expectation that HEPLISAV-B will become cash generative before the end of 2019,” said Eddie Gray, chief executive officer of Dynavax. “In addition, our studies of SD-101 in combination with pembrolizumab continue to generate consistent, encouraging results beyond those reported with monotherapy. We are evaluating multiple opportunities, including partnerships, expansion of tumor types under study and selection of best options for progression into registrational studies.”

Financial Results
Cash, cash equivalents and marketable securities totaled $180.2 million at September 30, 2018, compared to $216 million at June 30, 2018, with $75 million available from our term loan agreement.

Dynavax’s first commercial product, HEPLISAV-B, was launched in the first quarter of 2018 and net product revenue for the three and nine months ended September 30, 2018 were $1.5 million and $2.9 million, respectively. 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 was $3.9 million and $9.3 million for the three and nine months ended September 30, 2018 and consists of inventory reserves and fill, finish and overhead costs incurred after FDA approval for the vial presentation of HEPLISAV-B. Also included are costs associated with resuming operations at our manufacturing facility in Dusseldorf after receiving regulatory approval for the pre-filled syringe presentation, which costs previously were included in research and development expense.

Research and development expenses for the three months ended September 30, 2018 and 2017, were $16.8 million and $16.4 million, respectively. Research and development expenses for the nine months ended September 30, 2018 and 2017, were $52.1 million and $47.6 million, respectively. The increase in 2018 reflects increased compensation and related personnel costs related to the ongoing development of SD-101, DV281 and earlier stage oncology programs. Upon approval of pre-filled syringes in Q1, 2018, costs associated with resuming activities at our manufacturing facility in Dusseldorf were charged to cost of sales-product while costs incurred to manufacture HEPLISAV-B for commercial sale were accounted for as

inventory.

Selling, general and administrative expenses for the three months ended September 30, 2018 and 2017, were $15.8 million and $6.0 million, respectively. Selling, general and administrative expenses for the nine months ended September 30, 2018 and 2017 were $48.3 million and $18.1 million, respectively. The increase 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.

The net loss for the third quarter of 2018 was $40.5 million, or $0.65 per share, compared to $22.1 million, or $0.38 per share, for the third quarter of 2017. The net loss for the nine-month period ended September 30, 2018 was $118.9 million, or $1.91 per share, compared to $67.7 million, or $1.36 per share, for the same period in 2017.

Conference Call and Webcast Information
Dynavax will hold a conference call today at 4:30pm ET/1:30pm PT. To access the call, participants must dial (866) 420-4066 in the U.S. or (409) 217-8237 internationally, and use the conference ID 5179228. 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's first commercial product, HEPLISAV-B® [Hepatitis B Vaccine (Recombinant), Adjuvanted], was approved by the United States Food and Drug Administration in November 2017 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, including projected sales and profitability levels, conduct of clinical trials of SD-101, including results from the Phase 1b/2 trial, planned optimal dosage for the Phase 3 trial, and potential value of SD-101 across multiple tumor types. 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; 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 whether or not Dynavax and parties with whom we are collaborating 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 Quarterly Report on Form 10-Q for the quarter ended June 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 September 30,		Nine Months Ended September 30,	
	2018	**2017**	**2018**	**2017**
Revenues:				
Product revenues, net	$ 1,461	$ -	$ 2,880	$ -
Grant revenue	-	53	-	306
Total revenues	**1,461**	**53**	**2,880**	**306**
Operating expenses:				
Cost of sales - product	3,927	-	9,309	-
Cost of sales - amortization of intangible assets	3,823	-	8,538	-
Research and development	16,820	16,417	52,059	47,576
Selling, general and administrative	15,788	6,027	48,332	18,111
Restructuring	-	-	-	2,783
Total operating expenses	**40,358**	**22,444**	**118,238**	**68,470**
Loss from operations	(38,897)	(22,391)	(115,358)	(68,164)
Other income (expense):				
Interest income	1,047	429	2,940	809
Interest expense	(2,735)	-	(6,587)	-
Other income (expense), net	57	(166)	75	(378)
Net loss	**$ (40,528)**	**$ (22,128)**	**$ (118,930)**	**$ (67,733)**
Basic and diluted net loss per share	**$ (0.65)**	**$ (0.38)**	**$ (1.91)**	**$ (1.36)**
Weighted average shares used to compute basic and diluted net loss per share	**62,650**	**57,650**	**62,250**	**49,785**

DYNAVAX TECHNOLOGIES CORPORATION

SELECTED BALANCE SHEET DATA

(In thousands)

(Unaudited)

	September 30, 2018	**December 31, 2017**
Assets		
Cash, cash equivalents and marketable securities	$ 180,221	$ 191,854
Inventories	12,452	312
Property and equipment, net	16,933	16,619
Intangible assets, net	14,041	1,306
Goodwill	2,174	2,244
Other assets	10,567	6,450
Total assets	**$ 236,388**	**$ 218,785**

Liabilities and stockholders' equity		
Total current liabilities	$ 31,598	$ 18,593
Total long-term liabilities	107,777	643
Stockholders' equity	97,013	199,549
Total liabilities and stockholders' equity	**$ 236,388**	**$ 218,785**

Source: Dynavax Technologies Corporation