Dynavax Announces First Quarter 2019 Financial Results

May 8, 2019

- First quarter 2019 HEPLISAV-B® net product revenue of $5.6 million
- Conference call to be held today at 4:30 p.m. ET/1:30 p.m. PT

BERKELEY, Calif., May 08, 2019 (GLOBE NEWSWIRE) -- Dynavax Technologies Corporation (NASDAQ: DVAX), a fully-integrated biopharmaceutical company focused on discovering, developing and commercializing novel vaccines and immuno-oncology therapeutics, today reported financial results for the first quarter ended March 31, 2019.

"HEPLISAV-B net product revenue was $5.6 million for the first quarter of this year, which was in line with our expectations," said Eddie Gray, chief executive officer of Dynavax. "As the only two-dose hepatitis B vaccine, we are focused on making HEPLISAV-B the standard of care hepatitis B adult vaccine in the U.S. On the immuno-oncology development front, we will have three SD-101 data presentations at ASCO."

First Quarter and Recent Business Highlights

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

- First quarter 2019 sales of $5.6 million compared to $3.9 million in the fourth quarter 2018
- The company has achieved sales into 3 of the 4 top national retail pharmacy chains, and contracting efforts are underway to secure additional pharmacy partners
- More than 1,454 individual customers have purchased HEPLISAV-B since launch
- Only 4% of doses sold to date were to customers who have not reordered after at least 45 days
- 15 of the top 20 Integrated Delivery Networks (IDNs) have made HEPLISAV-B available to order
- 557 of the targeted 1,419 accounts have made HEPLISAV-B available to order, representing 50% of the targeted adult hepatitis B market
- 164 of the top 300 targeted customers have ordered HEPLISAV-B
- In May, the company announced the enrollment of the first patient in an open-label, single-arm study of HEPLISAV-B in adults with end-stage renal disease who are initiating or undergoing hemodialysis. The study is designed to evaluate immunogenicity and safety.

Immuno-oncology

SD-101

Three Dynavax abstracts have been accepted for presentation at the ASCO Annual Meeting 2019 in June.

- Abstract #6039, "Phase 1b/2, open label, multicenter study of intratumoral SD-101 in combination with pembrolizumab in anti-PD-1 treatment naive patients with recurrent or metastatic head and neck squamous cell carcinoma (HNSCC)"
- Abstract #9534, "Phase 1b/2, open label, multicenter, study of the combination of SD-101 and pembrolizumab in patients with advanced melanoma who are naïve to anti-PD-1 therapy"
- Abstract #9555, "Phase 1b/2, open label, multicenter, study of the combination of SD-101 and pembrolizumab in patients with advanced/metastatic melanoma resistant to anti-PD-1/PD-L1 therapy"

DV281

Dynavax presented phase 1b data on inhaled DV281 TLR9 agonist at the 2019 AACR Annual Meeting. Key highlights from the clinical data presentation include:

- In this safety study, two doses of DV281 monotherapy followed by combination with nivolumab was well tolerated
- Inhalation of DV281 leads to dose-dependent target engagement as measured by induction of IFN-regulated genes at all evaluated dose levels
- DV281 plus nivolumab demonstrates early signs of antitumor activity in heavily pretreated patients

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 first quarter of 2019 was $5.6 million, compared to $0.2 million for the first quarter of 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 first quarter of 2019 was $1.8 million, compared to $0.2 million for the first quarter of 2018. Included in cost of sales **-** product, are fill, finish and overhead costs for HEPLISAV-B incurred after U.S. Food and Drug Administration (FDA) approval. A higher percentage of HEPLISAV-B inventory sold in 2019 used components manufactured after FDA approval compared to 2018, when most of the expense associated with product sold was expensed to research and development prior to approval. The company expects its HEPLISAV-B cost of sales to increase in future periods as it produces and then sells inventory that reflects the full cost of manufacturing the product.

R&D Expenses. Research and development expenses for the first quarter of 2019 were $21.2 million, compared to $19.0 million for the first quarter of 2018. The increase reflects additional personnel and clinical trial expense for ongoing development of SD-101 and DV281.

SG&A. Selling, general and administrative expenses for the first quarter of 2019 were $18.3 million, compared to $16.9 million for the first quarter of 2018. The increase was due primarily to additional personnel in support of HEPLISAV-B commercial activities.

Net Loss. Net loss for the first quarter of 2019 was $39.7 million, or $0.62 per basic and diluted share, compared to a net loss of $39.0 million, or $0.63 per basic and diluted share, for the first quarter of 2018.

Cash Position. Cash, cash equivalents and marketable securities totaled $183.2 million at March 31, 2019, compared to $145.5 million at December 31, 2018. In March 2019, Dynavax exercised its option to draw down $75 million of non-dilutive capital under its existing term loan agreement with CRG Servicing LLC.

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 may dial (855) 327-6837 (domestic) or (631) 891-4304 (international) and refer to conference ID 10006654. 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 DV281
DV281 is Dynavax's proprietary investigational TLR9 agonist designed specifically for focused delivery to primary lung tumors and lung metastases. DV281 is similar in biological activity and mechanism of action to Dynavax's Phase 2 immunotherapy candidate, SD-101, but has been optimized for administration as an inhaled therapy. Both SD-101 and DV281 activate plasmacytoid dendritic cells which then stimulate T cells specific for antigens released from dying tumor cells. TLR9 agonists such as DV281 and SD-101 have been shown to stimulate potent Type 1 interferon induction along with maturation of dendritic cells to effective antigen-presenting cells; both activities are important for the induction of effective anti-tumor immunity.

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. 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 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 timing of fully-enrolling and completing the HEPLISAV-B study of adults with end-stage renal disease and the results of the study, 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, 2018 and in our Quarterly Report on Form 10-Q for the quarter ended March 31, 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.

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

[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 March 31,	
	2019	**2018**
Revenues:		
Product revenues, net	$ 5,627	$ 165
Collaboration revenue	146	-
Total revenues	**5,773**	**165**
Operating expenses:		
Cost of sales – product	1,800	205
Cost of sales - amortization of intangible assets	2,273	2,417
Research and development	21,206	18,966
Selling, general and administrative	18,348	16,891
Total operating expenses	**43,627**	**38,479**
Loss from operations	(37,854)	(38,314)
Other income (expense):		
Interest income	735	740
Interest expense	(2,734)	(1,161)
Other income (expense), net	181	(223)
Net loss	**$ (39,672)**	**$ (38,958)**
Basic and diluted net loss per share	**$ (0.62)**	**$ (0.63)**
Weighted average shares used to compute basic and diluted net loss per share	**63,778**	**61,744**

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

	March 31, 2019	**December 31, 2018**
Assets		
Cash, cash equivalents and marketable securities	$ 183,216	$ 145,536
Inventories, net	27,569	19,022
Property and equipment, net	25,305	17,064
Intangible assets, net	9,445	11,717
Operating lease right-of-use assets	33,505	-
Goodwill	2,102	2,144
Other assets	15,458	15,401
Total assets	**$ 296,600**	**$ 210,884**
Liabilities and stockholders' equity		
Total current liabilities	$ 42,251	$ 38,033
Total long-term liabilities	211,190	109,786
Stockholders' equity	43,159	63,065
Total liabilities and stockholders' equity	**$ 296,600**	**$ 210,884**

Contact:
Heather Rowe

Vice President, Investor Relations & Corporate Communications
hrowe@dynavax.com
510-665-7269

Source: Dynavax Technologies Corporation