Dynavax Announces Third Quarter 2019 Financial Results

November 6, 2019

- Third quarter 2019 HEPLISAV-B® net product revenue of $10.2 million
- Raising revenue expectation range to $34-$36 million for full year 2019
- Conference call to be held today at 4:30 p.m. ET/1:30 p.m. PT

EMERYVILLE, Calif., Nov. 06, 2019 (GLOBE NEWSWIRE) -- Dynavax Technologies Corporation (NASDAQ: DVAX), a biopharmaceutical company focused on developing and commercializing novel vaccines, today reported financial results for the third quarter ended September 30, 2019.

"HEPLISAV-B net product revenue was $10.2 million for the third quarter of this year, prompting us to raise our expectations for net product revenue to between $34-$36 million for full year 2019," commented Ryan Spencer, Co-President for Dynavax. "We are very pleased with our progress in transforming Dynavax into a commercially-focused vaccine company and excited by the traction that HEPLISAV-B is gaining in the market."

Mr. Spencer added, "We estimate that approximately 2.5 million adults are vaccinated against hepatitis B annually in the U.S. resulting in a current total market opportunity, based on our list price for HEPLISAV-B, of approximately $500 million. HEPLISAV-B is the only approved 2-dose adult hepatitis B vaccine and consistently protected more than 90% of adult patients in clinical studies. Based on this clinical profile and our commercial experience to date, we believe HEPLISAV-B has the potential to become the standard of care adult hepatitis B vaccine in the U.S."

Third Quarter and Recent Business Highlights

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

- Third quarter 2019 sales of $10.2 million compared to $8.3 million in the second quarter 2019
- Market share in accounts targeted by the field sales team increased to 18% in the third quarter of 2019 from 13% in the second quarter 2019
- The Company has established purchase agreements with 9 of the top 10 retail pharmacy chains
- In October, Kaiser Permanente Southern California completed accrual of patients in the on-going HEPLISAV-B post-marketing studies

Third Quarter Financial Results

Product Revenue, Net. HEPLISAV-B was launched in the first quarter of 2018. Net product revenue for the third quarter of 2019 was $10.2 million, compared to $1.5 million for the third quarter of 2018. Net product revenue for the nine months ended September 30, 2019, was $24.1 million, compared to $2.9 million for the nine months ended September 30, 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 third quarter of 2019 was $3.8 million, compared to $3.9 million for the third quarter of 2018. Cost of sales - product, for the nine months ended September 30, 2019, was $7.8 million, compared to $9.3 million for same period in 2018.

R&D Expenses. Research and development (R&D) expenses for the third quarter of 2019 were $12.7 million, compared to $16.8 million for the third quarter of 2018. R&D expenses for the nine months ended September 30, 2019, were $50.1 million, compared to $52.1 million for the same period in 2018. The decrease in R&D expenses is due to the reduction in R&D headcount and related expenses and the winding down of oncology clinical trial activity resulting from the Company's strategic organizational restructuring around its vaccine business that was implemented in May 2019. R&D expenses in the third quarter of 2019 included approximately $2.9 million in external expenses related to oncology programs. These expenses are expected to continue to decrease over the next three quarters as these activities are completed.

SG&A Expenses. Selling, general and administrative (SG&A) expenses for the third quarter of 2019 were $18.5 million, compared to $ 15.8 million for the third quarter of 2018. SG&A expenses for the nine months ended September 30, 2019, were $54.7 million, compared to $48.3 million for the same period in 2018. The increase for both the three and nine months ended September 30, 2019 compared to 2018 was due primarily to increases in sales and marketing activities and higher facility costs due to increased lease expense and an increase in facility related overhead allocation to SG&A functions following the May restructuring. In addition, the third quarter of 2019 includes payments for completion of certain milestones in the HEPLISAV-B post marketing study.

Restructuring. In May 2019, the Company implemented a strategic organizational restructuring, principally to align operations around its vaccine business and significantly curtail further investment in its immuno-oncology business. In connection with the restructuring, the Company reduced its workforce by approximately 80 positions, or approximately 36%, of U.S.-based personnel. The Company expects the restructuring to be substantially complete and the costs incurred and paid by December 31, 2019.

The total restructuring cost is estimated to be $13.5 million, of which $6.4 million is related to severance, other termination benefits and outplacement services, $4.1 million is related to stock-based compensation expense as a result of accelerated vesting of stock awards and extension of exercise period of stock options and $3.0 million is related to accelerated depreciation. During the three months ended September 30, 2019, the Company recognized restructuring charges of $3.9 million and the remaining $0.8 million is expected to be recognized by the end of 2019.

Net Loss. Net loss allocable to common stockholders for the third quarter of 2019 was $36.7 million, or $0.49 per basic and diluted share, compared to a net loss of $40.5 million, or $0.65 per basic and diluted share, for the third quarter of 2018. Net loss allocable to common stockholders for the nine months ended September 30, 2019, was $119.1 million, or $1.75 per basic and diluted share, compared to a net loss of $118.9 million, or $1.91 per

basic and diluted share for the nine months ended September 30, 2018.

Cash Position. Cash, cash equivalents and marketable securities totaled $174.9 million at September 30, 2019.

2019 HEPLISAV-B Revenue Expectations
Dynavax expects HEPLISAV-B® net product revenue of $34-$36 million for the full year 2019, an increase from its previous expectation of $32-$36 million.

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 800-479-1004 (domestic) or 720-543-0206 (international) and refer to conference ID 5687867. 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 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 expectations for 2019 HEPLISAV-B revenues, statements regarding future potential market opportunity for HEPLISAV-B, and statements regarding the timing of the completion of the Company's restructuring and payment of costs incurred and paid in connection with the restructuring. 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 full year 2019 HEPLISAV-B net product revenue will meet our expectations, 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;, 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 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.

Contacts:
Nicole Arndt, Senior Manager, Investor Relations
narndt@dynavax.com
510-665-7264

Derek Cole, President
Investor Relations Advisory Solutions
derek.cole@IRadvisory.com

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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 September 30,	Nine Months Ended September 30,

	2019	2018	2019	2018
Revenues:				
Product revenues, net	$ 10,158	$ 1,461	$ 24,086	$ 2,880
Other revenue	417	-	563	-
Total revenues	**10,575**	**1,461**	**24,649**	**2,880**
Operating expenses:				
Cost of sales – product	3,824	3,927	7.765	9,309
Cost of sales - amortization of intangible assets	2,324	3,823	6,894	8,538
Research and development	12,660	16,820	50,062	52,059
Selling, general and administrative	18,459	15,788	54,668	48,332
Restructuring	3,937	-	12,714	-
Total operating expenses	**41,204**	**40,358**	**132,103**	**118,238**
Loss from operations	(30,629)	(38,897)	(107,454)	(115,358)
Other income (expense):				
Interest income	890	1,047	2,604	2,940
Interest expense	(4,779)	(2,735)	(12,111)	(6,587)
Sublease income	891	-	891	-
Other income, net	168	57	226	75
Net loss	(33,459)	(40,528)	(115,844)	(118,930)
Preferred stock deemed dividend	(3,267)	-	(3,267)	-
Net loss allocable to common stockholders	**$ (36,726)**	**$ (40,528)**	**$ (119,111)**	**$ (118,930)**
Basic and diluted net loss per share allocable to common stockholders	**$ (0.49)**	**$ (0.65)**	**$ (1.75)**	**$ (1.91)**
Weighted average shares used to compute basic and diluted net loss per share allocable to common stockholders	**75,106**	**62,650**	**68,032**	**62,250**

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

	September 30, 2019	December 31, 2018
Assets		
Cash, cash equivalents and marketable securities	$ 174,946	$ 145,536
Inventories, net	39,356	19,022
Property and equipment, net	31,461	17,064
Intangible assets, net	4,823	11,717
Goodwill	2,045	2,144
Other assets	48,384	15,401
Total assets	**$ 301,015**	**$ 210,884**
Liabilities and stockholders' equity		
Total current liabilities	$ 46,348	$ 38,033
Total long-term liabilities	215,511	109,786
Stockholders' equity	39,156	63,065
Total liabilities and stockholders' equity	**$ 301,015**	**$ 210,884**

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Source: Dynavax Technologies Corporation