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Dynavax Regains Full Rights to Investigational TLR 7/9 Inhibitor DV1179 Following Expiration of Collaboration With GSK

BERKELEY, CA -- (Marketwired) -- 11/28/14 -- Dynavax Technologies Corporation (NASDAQ: DVAX) today announced that it has regained full rights to DV1179, an investigational bifunctional inhibitor of toll-like receptors (TLR) 7 and 9. This resulted from the expiration of the Research and Development Collaboration and License Agreement with GSK originally executed in 2008. Dynavax will now have global rights to continue the development of DV1179 and other TLR 7/9 inhibitors for all indications.

Under the collaboration, Dynavax conducted a Phase 1 study of DV1179 to assess its safety and tolerability in healthy volunteers followed by a Phase 1b/2a study of safety and pharmacodynamics in patients with active systemic lupus erythematosus (SLE). In the SLE study, doses up to 60 mg/week for 8 weeks were well tolerated and the most common adverse events were injection site reactions, but DV1179 did not meet the pharmacodynamic endpoints related to reduction in interferon alpha-regulated genes. Following completion of the Phase 1b/2a study, GSK declined to exercise its option to license DV1179.

Nonclinical data suggest that DV1179 may have utility in a range of other indications and Dynavax is actively assessing opportunities for further development of this well-characterized therapeutic product candidate. In particular, promising data have been generated in animal models of sterile inflammation, suggesting potential use of TLR 7 and 9 inhibitors, such as DV1179, in treatment of conditions including autoimmune pancreatitis and nonalcoholic steatohepatitis (NASH). Dynavax is also assessing the potential of DV1179 in autoimmune diseases with localized rather than diffuse systemic manifestations such as scleroderma and dermatomyositis.

About Dynavax

Dynavax, a clinical-stage biopharmaceutical company, uses TLR biology to discover and develop novel vaccines and therapeutics in the areas of infectious and inflammatory diseases and oncology. Dynavax's lead product candidate is HEPLISAV-B, a Phase 3 investigational adult hepatitis B vaccine. For more information visit www.dynavax.com.

Forward Looking Statements

This press release contains "forward-looking statements," including statements related to potential future development of DV1179 and other TLR 7/9 inhibitors. 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 results of completed studies can be replicated in human studies, difficulties or delays in discovery or development, initiation and completion of preclinical or clinical studies, the results of those studies and the impact of those results on the initiation and completion of subsequent studies and issues arising in the regulatory process; our ability to obtain additional financing to support our operations; and other risks detailed in the "Risk Factors" section of our current periodic reports filed with the SEC. 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 the Company's current periodic reports with the SEC.

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Source: Dynavax Technologies

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