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Dynavax and AstraZeneca to Advance TLR9 Agonist for Treatment of Asthma Into Phase 2a Clinical Study

BERKELEY, CA -- (Marketwired) -- 12/08/14 -- Dynavax Technologies Corp. (NASDAQ: DVAX) today announced that the Company and AstraZeneca AB ("AstraZeneca") signed an amendment to the existing Research Collaboration and License Agreement under which AstraZeneca will fully fund and Dynavax will conduct a Phase 2a safety and efficacy trial of AZD1419 in patients with asthma.

AZD1419 is a proprietary, second-generation TLR9 agonist CpG oligodeoxynucleotide formulated for inhalation use. The decision to accelerate this potential disease-modifying therapeutic into Phase 2, eliminating the previously planned Phase 1b study, was based on the positive results of a Phase 1a study in 45 healthy volunteers. The primary study objective was assessment of the safety of 4 weekly doses of AZD1419 or placebo. Ascending doses were well tolerated with no serious adverse events observed in treated subjects. Additional endpoints assessing pharmacodynamics were met, with dose-dependent induction of interferon-regulated genes in sputum and blood cells.

Dynavax intends to initiate the Phase 2a study in asthma patients in the first half of 2015 and a milestone is payable on its initiation. Remaining potential milestone payments to Dynavax total approximately \$100 million. In addition, Dynavax will receive royalties on worldwide sales of any approved products resulting from the collaboration and will have the opportunity to co-promote in the United States.

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.

About AstraZeneca

AstraZeneca is a global, innovation-driven biopharmaceutical business that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of cardiovascular, metabolic, respiratory, inflammation, autoimmune, oncology, infection and neuroscience diseases. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information please visit: www.astrazeneca.com.

Forward Looking Statements

This press release contains "forward-looking statements," including statements related to expected payments under our AstraZeneca agreement and the expected initiation of a Phase 2a trial. 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 the study will receive timely regulatory approval to proceed or results of completed studies can be replicated in further studies as well as difficulties or delays in discovery or development, initiation and completion of 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; achieving our AstraZeneca agreement objectives; 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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