# STANDARD TERMS AND CONDITIONS OF SALE HEPLISAV-B Purchase Program

These Standard Terms and Conditions of Sale and the Enrollment Letter ("Terms") apply to all purchases and returns of HEPLISAV-B (the "Product") through the HEPLISAV-B Purchase Program (the "Program"). These Terms only apply to customers that are currently eligible to purchase Product under the Program ("Eligible Customers"). Dynavax Technologies Corporation ("Dynavax") may modify the Terms or discontinue the Program at any time in its sole discretion.

- 1. **Eligible Customers**. To be eligible to purchase the Product under the Program, Eligible Customers must: (a) complete the HEPLISAV-B Purchase Program Enrollment Letter ("Enrollment Letter"), (2) must not be affiliated with a group purchasing organization with which Dynavax is contracted ("Dynavax GPO"), and (3) must purchase through an Authorized Distributor (defined below in Section 3).
- 2. **Authorized Distributors.** Eligible Customers must purchase Products exclusively through Dynavax's authorized Product distributors ("**Authorized Distributors**") only for use in the United States. The current list of Authorized Distributors is available from HEPLISAV-B Access Navigator by calling 1-84-HEPLISAV (1-844-375-4728) and will be updated from time to time by Dynavax. Eligible Customer shall not be entitled to the Program Price (defined in Section 2) if Products are purchased from non-Authorized Distributors.

# 3. Program Price.

- 3.1. Eligible Customer may purchase the Product at a discounted rate off of WAC offered at the time an Eligible Customer orders the Product ("Discount Rate"). "WAC" or "Wholesale Acquisition Cost" shall mean the published list price for Product charged by Dynavax to purchasing wholesalers, excluding payment terms, such as prompt payment or other payments, discounts, credits, chargebacks, or freight charges. The WAC is subject to change by Dynavax at any time and from time to time without notice to Eligible Customers. Changes to WAC shall be effective immediately upon communication of the change to the Authorized Distributors. Dynavax may adjust the Discount Rate from time to time in its sole discretion; provided that, prior written notice is provided to Eligible Customers pursuant to Section 15 hereof. Changes to the Discount Rate shall be effective immediately upon provision of notice to Eligible Customers. The program price is equal to WAC minus the Discount plus the applicable vaccine excise tax (the "Program Price"). In the event of a change to any component of the Program Price, Eligible Customer acknowledges that the new Program Price may not be applied retroactively to existing inventory on hand.
- 3.2. Notwithstanding anything to the contrary in the foregoing, Eligible Customer understands and agrees that Authorized Distributors may charge distribution or other fees in addition to the Program Price and that Dynavax has no control over any such fees.

- 3.3. Program Price will be made available to Eligible Customers via a chargeback system through an Authorized Distributor of Eligible Customer's choice. Eligible Customers shall provide Dynavax a complete list of its selected Authorized Distributors, including contact names, addresses, telephone numbers, fax numbers, and e-mail addresses (if applicable). Eligible Customer will provide written notice of any change to the list of such selected Authorized Distributors to Dynavax within thirty (30) days of such change.
- 3.4. Dynavax is responsible for notifying all of such selected Authorized Distributors of the products and pricing included in the Program.

#### 4. Returns and Recalls.

- 4.1. **Returns.** Eligible Customers may return Product to Dynavax in accordance with Dynavax's returned goods policy in effect at the time of the return. A copy of the current Returned Goods Policy is attached here to as <u>Exhibit A</u>. The Returned Goods Policy may be amended by Dynavax from time to time in its sole discretion.
- 4.2. **Recalls.** Dynavax shall reimburse Eligible Customers for any necessary and documented cost directly associated with any Product corrective action, withdrawal or recall requested by Dynavax or required by any governmental entity; provided that, such Eligible Customer follows Dynavax's instructions in regard to such Product corrective action, withdrawal, or recall.

## 5. Customer Obligations.

- 5.1. **Own Use**. Eligible Customer agrees that it will not directly or indirectly cause or knowingly allow Products to be sold to or used by any party other than Eligible Customer or their end user customers/patients. This provision will be interpreted to require Products purchased hereunder to be used solely in conjunction with the principal business of the Eligible Customers and to mean that Products purchased hereunder will not be used for resale to third parties or distributed, sold, or transferred to any party other than Eligible Customer or their end user customers/patients.
- 5.2. **Discount Reporting**. Eligible Customer acknowledges that the Program Price represents a discount on Products. Eligible Customer shall properly and accurately account for, disclose and report the discounts provided under the Program in accordance with the requirements of all applicable federal and state laws, including the federal healthcare anti-kickback statute, Section 1128(B)(b) of the Social Security Act (42 U.S.C. § 1320a-7b(b)) and its discount safe harbor regulations (42 C.F.R. § 1001.952(h)), and applicable payers reimbursement policies and requirements. In particular, Eligible Customer will (i) fully and accurately disclose such discounts in accordance with, and to the extent required by, the discount safe harbor regulations, and (ii) provide, upon request by the U.S. Secretary of Health and Human Services, a State Medicaid agency or any other federal state health care program, complete information concerning the amount or value of the discounts received hereunder.

## 6. Dynavax Warranty.

- 6.1. Dynavax represents and warrants that the Products at the time of sale and delivery by Dynavax are in material conformity with the Federal Food, Drug and Cosmetic Act, as amended, and the regulations promulgated thereunder. AS ELIGIBLE CUSTOMER'S SOLE REMEDY AND DYNAVAX' SOLE LIABILITY FOR A BREACH OF THE FOREGOING WARRANTY, DYNAVAX SHALL, IN ITS DISCRETION, EITHER REPLACE A PRODUCT THAT FAILS TO CONFORM TO THE FOREGOING WARRANTY OR REFUND TO CUSTOMER THE AMOUNT PAID TO DYNAVAX FOR SUCH NON-CONFORMING PRODUCT.
- 6.2. EXCEPT AS EXPRESSLY SET FORTH IN THIS <u>SECTION 6</u>, DYNAVAX MAKES NO OTHER WARRANTIES, WHETHER EXPRESS, IMPLIED OR STATUTORY, INCLUDING BUT NOT LIMITED TO ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.
- 7. **Records; Audit.** Eligible Customer shall maintain accurate and complete records related to Product purchases through the Program for at least two (2) years following the purchase of Products, or longer if required by law. For a period of two (2) years after the Eligible Customers last purchase under the Program, Dynavax shall have the right to audit, or to engage a mutually acceptable independent firm to audit Eligible Customers' compliance with its obligations pursuant to these Terms. Dynavax or such independent firm shall only have access to information as is necessary to verify the performance and compliance with obligations pursuant to this Agreement, provided access to such information is in compliance with applicable state and/or federal privacy laws. Approval of an independent accounting firm or auditor may not be unreasonably withheld.

## 8. Termination

- 8.1. **Termination for Cause**. In the event of a material breach of these Terms by an Eligible Customer, Dynavax shall give written notice thereof to the Eligible Customer. If such breach is not cured in all material respects within thirty (30) days after such notice, Dynavax may determine that the Eligible Customers can no longer participate in the Program as of the termination date set forth in written notice provided to the Eligible Customer.
- 8.2. **Termination for Convenience**. Either party may terminate these Terms for any reason upon thirty (30) days prior written notice to the other party.
- 8.3. **Product Termination.** Notwithstanding anything to the contrary set forth in these Terms, Dynavax may immediately terminate these Terms and the Program as to the Product, if (i) Dynavax discontinues the manufacture, sale or distribution of such Product in the United States, (ii) a patent covering such Product expires; (iii) such Product becomes available as a generic drug, (iv) Dynavax stops co-promoting with or licensing such Product from another person, or (v) Dynavax otherwise transfers to another person or no longer possesses adequate rights in and to such Product. Dynavax

shall give to Customer such notice as is reasonable under the circumstances, specifying where practical the date upon which the Program shall no longer be offered (the "**Program Termination Date**"). The Program Price for such Product shall not be available to Eligible Customer for Product purchased after the Program Termination Date.

8.4. **Effect of Termination**. In the event of termination of the Program for any reason, Dynavax shall no longer be obligated to offer the Program Price on any Products purchased or invoiced after the effective date of such termination.

## 9. **Indemnification.**

- 9.1. **Indemnification**. Both Dynavax and Eligible Customer shall indemnify, defend and hold harmless the other party from and against any and all charges, complaints, actions, suits, proceedings, hearings, investigations, claims and demands (collectively, "Claims") of third parties, and all associated losses, costs, expenses, and fees (including, without limitation, reasonable attorney fees), to the extent arising out of or related to (i) the negligence, willful misconduct or fraud of such party in performing its obligations under these Terms, or (ii) the breach by such party of any of its representations, warranties, covenants, or obligations contained in these Terms.
- 9.2. **Notice and Opportunity to Defend**. The indemnified party shall give the indemnifying party notice of any Claim upon which the indemnified party intends to base an indemnification claim (an "**Indemnity Claim**"). The indemnifying party has the right to control the defense, settlement or disposition of any Indemnity Claim using counsel of its choice and on terms that the indemnifying party deems appropriate, except that the indemnified party may, at its own expense, participate in that defense, settlement or disposition using counsel of its own choice. With respect to the defense, settlement or disposition of an Indemnity Claim, the indemnified party shall provide the indemnifying party, at the indemnifying party's expense, with reasonable assistance and cooperation as reasonably requested by the indemnifying party. Without limiting the generality of the foregoing, the indemnifying party may not settle or otherwise dispose of any Indemnity Claim without the indemnified party's prior written consent, such consent not to be unreasonably withheld or delayed.
- 10. Limitation of Liability. EXCEPT IN THE EVENT OF FRAUD OR WILFULL MISCONDUCT, NEITHER DYNAVAX NOR ELIGIBLE CUSTOMER HEREUNDER SHALL BE LIABLE TO THE OTHER PARTY FOR ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL, SPECIAL OR PUNITIVE DAMAGES ARISING OUT OF OR RELATING TO THIS AGREEMENT, REGARDLESS OF WHETHER SUCH DAMAGES ARE BASED IN CONTRACT, TORT (INCLUDING NEGLIGENCE), OR OTHERWISE, AND EVEN IF A PARTY HEREUNDER WAS APPRISED OF THE POSSIBILITY OF SUCH DAMAGES.
- 11. **Agreement.** The terms set forth in this document take precedence over any conflicting or inconsistent terms contained in any other quotation purchase order, acknowledgement, invoice or other document issues by anyone other than Dynavax, except as otherwise

provided expressly herein. Any terms or conditions proposed by any party other than Dynavax that are inconsistent with, or in addition to, these Terms shall be void and of no effect unless Dynavax agrees to such terms and conditions in writing signed by Dynavax. No additional terms are implied by usage of trade, by course of dealing, or by course of performance.

- 12. **Modification.** Notwithstanding anything else to the contrary in these Terms, Dynavax has the unilateral right to modify these Terms at any time at its sole discretion; provided that, written notice is provided to Eligible Customers pursuant to Section 15 hereof. In the event that Dynavax modifies the Program, the new terms and conditions will automatically apply to the Eligible Customer as the effective date of the modification. Except to the extent otherwise specified herein, the Terms in effect at the time of the Product order shall govern purchases under the Program.
- 13. **Severability**. In the event any term or provision of these Terms is declared illegal or unenforceable or in conflict with any law or regulation, the validity of any other term or provision of these Terms shall not be affected thereby.
- 14. Compliance with Laws. Dynavax and Eligible Customers shall comply with all federal, state and local laws and regulations applicable to its operations and/or its participation in the Program, including without limitation (a) all federal and state health care anti-fraud and abuse laws, and (b) any and all applicable federal and state laws, rules, regulations, and registration or approval requirements governing the storage, sales, distribution and use of Products. Without limiting the foregoing, Eligible Customer shall at all times, hold, handle, warehouse, store, ship, distribute, and otherwise dispose of the Products in a manner consistent with these Terms, all regulatory approvals, applicable laws, rules, regulations and requirements, the Product labeling, and any handling instructions received from Dynavax.
- 15. **Notice**. All notices under this Agreement shall be in writing, shall refer specifically to these Terms, and shall be (a) hand delivered or sent by express courier service, costs prepaid, (b) sent by facsimile to the respective addresses specified below (or to such other addresses as may be specified by notice to the other party), or communicated via email. All notices shall be effective upon receipt. If Eligible Customer, the contact information set forth in the Enrollment Letter shall be utilized. Notices to Dynavax should be sent to 2929 Seventh Street, Suite 100, Berkeley, CA 94710, Attn: General Counsel, Fax: 510-848-1327, Phone: 510-848-5100.
- 16. **Waiver**. Any failure of Dynavax or Eligible Customer to comply with any obligation, covenant, agreement or condition herein contained may be expressly waived, in writing only, by the other party hereto and such waiver shall be effective only in the specific instance and for the specific purpose for which it was made or given. Such waiver shall not constitute an amendment or modification of this Agreement.
- 17. **Entire Document**. These Terms and the Enrollment Letter constitute the entire agreement between Dynavax and the Eligible Customer in relation to the subject matter hereof and

- supersedes all prior agreements and understandings of any nature between the parties in relation hereto.
- 18. **Assignment**. This Agreement may not be assigned or otherwise transferred (by operation of law or otherwise) by Eligible Customer without the prior written consent of Dynavax, which consent shall not be unreasonably withheld. These Terms shall be binding upon and shall inure to the benefit of the permitted successors and assigns of the parties hereto.
- 19. **Insurance**. Eligible Customer will maintain in effect while purchasing under the Program a comprehensive general liability policy. This comprehensive general liability policy shall be in an amount not less than One Million Dollars (\$1,000,000) per incident and Three Million Dollars (\$3,000,000) in the aggregate. Eligible Customer agrees to provide Dynavax with a certificate of such insurance upon Dynavax' request.
- 20. Force Majeure. Neither Dynavax nor Eligible Customers shall be liable for delay or failure of performance occasioned by causes reasonably beyond its control, including but not limited to, failure of public utilities or common carrier, acts of God or the public enemy, declared or undeclared acts of war, terrorism, or civil unrest, destruction of production facilities and/or materials, fire, flood, unusually severe weather, explosion, earthquakes or volcanoes, or labor disturbances ("Force Majeure Event"). If either party is affected by a Force Majeure Event, the affected party shall give the other party written notice, which shall cause, without penalty to either party, all obligations under these Terms to be suspended for a period of sixty (60) days.
- 21. **Governing Law**. The Terms shall be governed by and construed according to the laws of the California without regard to conflicts or choice of law principles. Eligible Customers agree to submit to the jurisdiction of any competent federal or state court sitting in California.

#### **EXHIBIT A**

# RETURNED GOODS POLICY Effective December 1, 2017

This document is the Dynavax Technologies ("Dynavax") policy for all returns of product(s) purchased directly from Dynavax, or it's Authorized Distributors of Record ("ADRs") by entities licensed to dispense or distribute Dynavax's products ("Customer").

Non-Authorized wholesalers, distributors and customers who purchase products from ADRs are not eligible to return Dynavax's product(s) for credit.

#### **Returnable Items**

Eligible products must be returned in accordance with the Returned Goods Authorization ("RGA") instructions. Return credit will be issued at the original purchasing price. The following products are eligible for return:

- 1. Received by Customer in error: Product shipped in error by Dynavax may be returned, if applicable, for a full credit, including freight, when returned within ten (10) calendar days of receipt.
- 2. Ordered by Customer in error: Products ordered in error may be returned for credit, freight prepaid by Customer, when reported within ten (10) calendar days of receipt by the Customer. Restocking fees will be assessed based upon volume of the order error.
- 3. Expired product may be returned for credit, if preauthorized by Dynavax and accompanied by an RGA. Expired, unopened product must be received within twelve (12) months after expiration. In-dated, unopened product shipped directly to an ADR may be returned six (6) months prior to expiration. Expired product approved by Dynavax for return must be shipped freight prepaid within thirty (30) calendar days of authorization date in order to receive credit.
- 4. Dynavax will issue authorization for the return of eligible, unopened vials only. Credit will not be issued for partial vials except where mandated by state law.
- 5. If product has been discontinued by Dynavax and current inventory is not depleted within sixty (60) calendar days after discontinuation, such product shall be eligible for return by Customer if preauthorized by Dynavax.

## **Damaged in Transit and Shortages**

- 1. Received by Customer as damaged: Products received damaged from Dynavax may be returned for full credit including freight when reported within ten (10) calendar days of receipt by the Customer. If product is received damaged please have the transportation company note "damaged" or "broken" on the freight bill. Damaged product should remain in the original carton for inspection by Dynavax.
- 2. <u>Shortages:</u> Upon receipt of product, ADRs are requested to verify quantities of units received against original shipping documents by performing a physical count. Any discrepancies must be reported to Dynavax within ten (10) calendar days of receipt, at which time Dynavax may initiate an investigation or initiate credit processing.

#### **Recall Product**

1. Product associated with a Dynavax-initiated recall is eligible for return subject to specific terms of the recall notification and requested return actions. If a product recall occurs, only Dynavax-authorized recalls will be honored for return of product for credit and will be handled in accordance with HDMA recall standards for fees and costs. Specific instructions for each recall shall be disseminated to the appropriate entities. To qualify for a credit or product replacement, the returned product must meet the criteria noted in the recall notification issued by Dynavax.

## **Non-Returnable Items**

All products, other than those listed above, shall be deemed not returnable for return goods credit. Non-returnable products include, without limitation:

- a) Product returned without an RGA.
- b) Product that is not in the original packaging bearing the original manufacture label.
- c) Product that is returned more than six (6) months prior to the expiration date.
- d) Product that is twelve (12) months or more past the expiration date. Product expiration occurs on the last day of the month of the expiration month and year noted on the package/container. (Product may be returned for destruction, but no credit will be issued.)
- e) No partials will be accepted for credit except where mandated by state law.
- f) Product obtained other than through normal channels of distribution or purchased from a source other than an ADR of Dynavax.
- g) Product involved in a fire sale, sacrifice sale, bankruptcy, flood, or earthquake.
- h) Product deteriorated or damaged due to conditions beyond the control of Dynavax, such as improper storage, heat, cold, water, smoke, fire, negligence, etc.
- i) Product deleted from Product Compendia (e.g. First DataBank, MediSpan) for six (6) months or more.
- j) Non-original or repackaged product. This includes prescription and/or other labels added to and/or removed from the original manufacturer's product package/container.
- k) Product sold with specific understanding that it is non-returnable.
- 1) Merchandise that is obtained in violation of state and federal regulations.
- m) Product that has been donated (at no charge to Customer).
- n) Product that Dynavax determines, in its sole discretion, is otherwise adulterated, misbranded, or counterfeit.

In addition, a Certificate of Destruction does not qualify as an acceptable format for product return.

## **Additional Terms of Return**

- a) Product returned as part of new product promotions will be at original purchase price, unless otherwise specified in the promotion.
- b) No credit will be issued for administration, shipping or handling, including third party processing fees, with the exception of product received by Customer as damaged and product received by Customer in error as referenced above under Returnable Items.

- c) Deductions from invoices/payments may not be taken until a credit memo is issued by Dynavax. Unauthorized deductions for returns may result in held orders. Acceptance of returned product at Dynavax does not constitute Dynavax's acceptance for credit. All product information (including product identification, lot number and expiration date) will be verified before credit is issued.
- d) For items purchased or invoiced from a wholesaler, credit will be issued through the wholesaler.
- e) Returns are subject to final count and acceptance by Dynavax. Dynavax reserves the right to accept or reject the product for credit.
- f) Dynavax reserves the right to destroy, without recourse, all returned packages.
- g) Returns should be channeled through the original source of purchase. The original source of purchase is defined as the entity that was directly invoiced by Dynavax and the distributor of origin.
- h) Unauthorized returns may be destroyed without notice and not reimbursed.

# **Procedure for Returning Items**

- a) Customers must obtain an RGA for returns via phone from Dynavax Customer Service at 844-810-6523 or via fax at 844-810-6522 or via email at <a href="mailto:DynavaxReturns@dynavax.com">DynavaxReturns@dynavax.com</a>. Returns will not be processed without an RGA. RGAs expire thirty (30) calendar days from date issued.
- b) Return product to Dynavax Technologies at the following address:

Dynavax Technologies ("Dynavax")
Attn: Returned Goods Dept.
420 International Boulevard, Suite 500
Brooks, Kentucky 40109

- c) An itemized packing slip, with the information listed below and a RGA number, must accompany any returned product.
- d) If returning more than one box, each box should contain the RGA number and box number, i.e. "1/2, 2/2".
- e) Include the following information:

Product Name

Quantity for Each Product

Lot Numbers

Original WAC

Debit Memo Number

Billing Address

Shipping Address

Reason for Return

Contact Person Name, Phone Number and/or Email

Wholesale Account # (if applicable)

DEA # or State Pharmacy ID

**RGA** Number

# **Transportation Charges**

Transportation/shipping charges and insurance surrounding the RGA and return must be prepaid by Customer. Except where otherwise specified in this policy, Dynavax will not pay for, nor reimburse Customers for, any transportation costs, insurance costs, administration fees, handling fees, or third party processing fees incurred. Direct purchasing Customers are specifically prohibited from deducting from any invoice/payment any such return transportations costs, insurance costs, handling fees, or processing fees.

# **Exceptions**

Dynavax reserves the right to modify and make exceptions to this policy and to its implementation at any time, without notice, for any reason, including, due to business necessity or changes in applicable laws and regulations.