PRIALT® (ziconotide) intrathecal infusion (25 mcg/mL, 100 mcg/mL) PENTEC Free Trial Request Form with Pharmacy Syringe Preparation

FAX Pages 1 & 3 to: 1-610-624-1144

Phone: 1-833-Esteve-1 (833-378-3831)

PRIALT (ZICONOTIDE) INTRATHECAL INFUSION

Please see the PRIALT Important Safety Information, including BOXED WARNING, on pages 4 and 5.

PRESCRIBING PHYSICIAN

Name (first and last) _____

State License # _____

NPI # _____

DEA# _____

Street Address _____

City _____ State _____ ZIP _____

Office Contact _____

Telephone # _____

Fax _____

E-mail _____

PATIENT INFORMATION

Name (first and last) _____

DOB (MM/DD/YYYY) ____/____/____

Street Address _____

City _____ State _____ ZIP _____

Telephone # _____

E-mail (optional) _____

Trial Date (MM/DD/YYYY) ____/____/____

Additional Instructions: _____

PRESCRIPTION INFORMATION

Esteve will deliver a single vial of PRIALT® (ziconotide), to our compounding pharmacy partner to prepare as directed below:

Select: ☐ 1 syringe* ☐ 2 syringe*†

Select 1 of the following PRIALT monotherapy doses:

☐ 2.5 mcg per 1 mL ☐ 3.0 mcg per 1 mL ☐ 5.0 mcg per 1 mL ☐ Other PRIALT dose in syringe : _____ mcg in mL _____

Directions for Use: ☐ Use as directed ☐ Other _____

Preferred Shipping Location ☐ Same As Physician Address

Address _____ City _____ State _____ ZIP _____

*A single syringe cannot total > 25 mcg. †Both syringes must have the same dosage.

PATIENT CLINICAL INFORMATION

Primary Diagnosis _____ Primary ICD-10 _____

Secondary Diagnosis _____ Secondary ICD-10 _____

☐ No known hypersensitivity to ziconotide or any of its components

Other relevant medications, drug allergies, or health conditions _____

PHYSICIAN AUTHORIZATION

a. **By signing this document, I certify that the patient meets the eligibility requirements, it has been determined the compounded drug is necessary for the identified patient, and I have read and agree to the Program Terms.** I understand that this program is intended for the evaluation of PRIALT with my eligible patient to determine whether PRIALT is right for them. I authorize the agents of Esteve Pharmaceuticals to use the above information to provide the PRIALT Free Trial Program to my patient. I understand that the agents of Esteve Pharmaceuticals will keep this information confidential and will use it only for the PRIALT Free Trial Program. This usage may include information and follow-up about PRIALT. Neither I, my agents nor any other party will submit any portion of the Free Trial Program, supplies, or administration services for reimbursement to any third-party payer, including Medicare or Medicaid, either directly or indirectly. Provider verifies that they will not bill for products/services.

b. PhysicianSignature: _____

c. Date(MM/DD/YYYY) ____/____/____

d. The prescriber is to comply with his/her state-specific prescription requirements such as e-prescribing, state-specific prescription form, fax language, etc. Non-compliance with state-specific requirements could result in delay.

IMPORTANT NOTE: Patient Signature required on page 3.

INTERIM VERBAL CONSENT

1. **Verbal Consent Pending Written Authorization.** Where the patient wishes to enroll in the PRIALT Free Trial Program ("Program") but is not able to sign this Authorization at the time of enrollment, Esteve Pharmaceuticals LLC, its affiliates, and their representatives, agents, and contractors ("Company") may accept the patient's verbal consent, on an interim basis, to (i) enrollment in the Program; (ii) the Company's collection, use, and disclosure of the personal information that the patient, the patient's caregiver, or the Program provides, including contact, medical condition, and prescription information; and (iii) contact by the Company by mail, email, or telephone regarding the Program and the patient's medical condition, treatment, and care management.

2. **Conditions of Valid Verbal Consent.** Verbal consent is valid only where each of the following conditions is satisfied:
   - The Patient Authorization set forth in Section 2 has been read to the patient in full by a Program representative;
   - The patient has verbally confirmed that the patient understands the Authorization and agrees to its terms;
   - The Program representative has contemporaneously documented the verbal consent, including the date and time of the call, the name of the patient, the name of the representative, and the specific consents given [and, where call recording is available and permitted by applicable law, an audio recording of the consent];
   - A copy of this Authorization has been mailed or emailed to the patient within [three (3)] business days of the call; and
   - The Verbal Consent Documentation Record in Section 3 has been completed and retained by the Program.

3. **Duration of Verbal Consent.** Verbal consent under this Section is an interim measure only and remains valid until the earliest of: (i) the date the patient signs the written Authorization, which the Program will request at the patient's next visit to the patient's healthcare provider's office or through such other means as the patient and the Program may arrange; (ii) [sixty (60)] days from the date of the verbal consent; or (iii) the date the patient revokes consent. If a signed written Authorization has not been obtained by the expiration of this period, the Company will suspend further use and disclosure of the patient's personal information under this consent, except as necessary to document the consent and its expiration or as otherwise required or permitted by law.

4. **Written Authorization Remains Required.** Verbal consent does not replace the written Authorization. By providing verbal consent, the patient agrees that the Program may follow up with the patient, and with the patient's healthcare provider's office, to obtain the patient's written signature at the patient's next office visit. The patient's healthcare providers remain responsible for complying with applicable law, including HIPAA, with respect to any disclosure of the patient's protected health information, and nothing in this Section requires or requests any disclosure that applicable law does not permit prior to receipt of the patient's signed written Authorization.

5. **Revocation; No Conditioning.** The patient may revoke a verbal consent at any time, verbally by telephone to the Program or by written notice to the Company at the address in Section 2, except to the extent that action has already been taken in reliance on the consent. The patient's treatment and health plan benefits are not conditioned on whether the patient provides verbal consent or signs the Authorization.

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PATIENT AUTHORIZATION

a. By signing this Authorization, or by providing my verbal consent as documented by a Program representative in accordance with the Interim Verbal Consent Section, I authorize my healthcare providers (including my physicians, pharmacy, insurers and testing laboratories) to disclose my protected health information, including, but not limited to, personal information related to my medical condition, treatment, and management, as well as all information provided on this form including contact and any prescription information ("Personal Health Information"), to Esteve Pharmaceuticals LLC, its affiliates, and their representatives, agents and contractors ("Company") so that the Company may provide product to me under this free trial program, may communicate with me by mail, email, or telephone about my medical condition, treatment, and care management and as may be needed for Company's internal business purposes, including analytics. I understand that my treatment and health plan benefits will not be conditioned on whether I sign this Authorization. I understand that once disclosed to the Company, my Personal Health Information disclosed under this Authorization may be further disclosed by the recipient and may no longer be protected by federal privacy law, including HIPAA. This Authorization will expire within ten (10) years from today's date, unless a shorter period is provided by state law. I understand that I may revoke this Authorization at any time by sending written notice of revocation to Esteve Pharmaceuticals LLC at 89 Headquarters Plaza #350, Morristown, NJ 07960, except to the extent that action already has been taken in reliance on this Authorization. I understand that I have a right to receive a copy of this signed Authorization.

b. ☐ By checking this box, I consent to enroll in ESTEVE Embrace (the "Program") to discuss training and education questions related to my PRIALT prescription. I understand that my enrollment means that Esteve Pharmaceuticals will collect and use my personal information, including name, contact information, diagnosis and prescription information, to contact me regarding and administer my enrollment in the Program. I understand I can terminate my enrollment at any time and learn more about my privacy choices and how Esteve handles my personal information by requesting a copy of the privacy policy by emailing customercare@esteve.com.

c. **Signature of Patient**(Required) _____ **Date (MM/DD/YYYY)** ___/___/___

PROGRAM TERMS

- The Program Terms of the PRIALT Free Trial Program are unchanged by these interim verbal consent provisions and apply equally to patients enrolled by verbal consent.
- The PRIALT Free Trial Program provides adult patients with severe chronic pain a single trial dose of PRIALT.
- This free trial offer is solely intended to allow new patients to try PRIALT and to determine with their healthcare provider whether PRIALT is right for them. There is no obligation to continue use of PRIALT after the free trial has been completed.
- This free trial prescription is valid for one time only with no refills. For any future use, the patient must obtain a new prescription for PRIALT.
- To be eligible, patient must: 1) be an adult with an ICD-10 code verifying diagnosis of severe chronic pain; 2) be a patient for whom it has been determined that intrathecal therapy is warranted, and who is intolerant of or refractory to other treatment; and 3) be a new patient not currently using PRIALT and who has not previously enrolled in the PRIALT Free Trial Program.
- The PRIALT Free Trial Program cannot be exported or transferred in exchange for money, other property, and services.
- **No portion of the PRIALT Free Trial Program, or administration services may be submitted for reimbursement to any third-party payer, including Medicare or Medicaid, either directly or indirectly.**
- This program is only valid for residents of the United States, excluding Puerto Rico and other U.S. territories.
- Esteve Pharmaceuticals LLC reserves the right to change or discontinue this program at any time without notice.
- This is not a financial assistance nor cost savings program.

INSTRUCTIONS FOR COMPLETING THE FORM

- **Fill out all sections completely.**
- Do not submit to Esteve Pharmaceuticals any documentation other than this form.
- **Physician Authorization:** This is a prescription and requires a physician signature and date.
  - Stamps are NOT acceptable.
- **Patient Authorization:** The patient signature is required to allow personal health information to be shared by third parties to Esteve to facilitate access to PRIALT (fulfilling and coordinating delivery of medication, etc).
- FAX completed Pages 1 & 3 to 1-610-624-1144.

Please see the PRIALT Important Safety Information, including BOXED WARNING, on pages 4 and 5.

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INDICATION

PRIALT® (ziconotide) solution, intrathecal infusion is indicated for the management of severe chronic pain in adult patients for whom intrathecal (IT) therapy is warranted, and who are intolerant of or refractory to other treatment, such as systemic analgesics, adjunctive therapies, or IT morphine.

IMPORTANT SAFETY INFORMATION

BOXED WARNING: NEUROPSYCHIATRIC ADVERSE REACTIONS

- **PRIALT is contraindicated in patients with a preexisting history of psychosis. Severe psychiatric symptoms and neurological impairment may occur during treatment with PRIALT. Monitor all patients frequently for evidence of cognitive impairment, hallucinations, or changes in mood or consciousness. Discontinue PRIALT therapy in the event of serious neurological or psychiatric signs or symptoms.**

CONTRAINDICATIONS

PRIALT is contraindicated in patients with:

- A known hypersensitivity to ziconotide or any of its formulation components.
- A medical condition that would render intrathecal administration hazardous to the use of intrathecal analgesia such as the presence of infection at the microinfusion injection site, uncontrolled bleeding diathesis, and spinal canal obstruction that impairs circulation of cerebrospinal fluid (CSF).
- A pre-existing history of psychosis.

ADDITIONAL IMPORTANT SAFETY INFORMATION

Cognitive and Neuropsychiatric Adverse Reactions (see BOXED WARNING)

- PRIALT may cause or worsen depression, with the risk of suicide in susceptible patients.
- Patients with pretreatment for psychiatric disorders may be at an increased risk of psychiatric disturbances.
- Cognitive impairment such as confusion (particularly in the elderly ≥65 years), memory impairment, speech disorder, aphasia, thinking abnormal, and amnesia, along with decreased alertness/unresponsiveness, may appear gradually after several weeks of treatment. Reduce the dose of PRIALT or discontinue the use of PRIALT if signs or symptoms of cognitive impairment develop but consider other contributing causes. The cognitive effects of PRIALT are generally reversible within 2 weeks after drug discontinuation.
- PRIALT therapy can be interrupted or discontinued abruptly without evidence of withdrawal effects in the event of serious neurological or psychiatric signs or symptoms.
- Concomitant use of central nervous system (CNS) depressants with PRIALT may have additive effects and require dosage adjustments.

Reduced Level of Consciousness and Driving, Operating Machinery

- In clinical trials, 2% of PRIALT-treated patients became unresponsive or stuporous. Patients are at higher risk for depressed levels of consciousness with concomitant use of antiepileptics, neuroleptics, sedatives, or diuretics.
- PRIALT has been associated with cognitive impairment and decreased alertness/unresponsiveness. Caution patients against engaging in hazardous activities that require complete mental alertness or motor coordination.
- If reduced levels of consciousness occur, discontinue PRIALT until the event resolves, consider other etiologies (e.g., meningitis), and discontinue other CNS-depressant drugs as clinically appropriate.

(Continued on next page)

Elevation of Serum Creatine Kinase

- In clinical trials, 40% of patients had serum creatine kinase (CK) levels above the upper limit of normal (ULN) and 11% had CK levels >3 times the ULN. Monitor serum CK levels periodically. In the event of new neuromuscular symptoms, evaluate patients clinically and obtain CK measurements. If symptoms continue and CK levels remain elevated or continue to rise, reduce the dose, or discontinue the use of PRIALT.

Withdrawal From Opiates

- PRIALT is not an opiate and cannot prevent or relieve the symptoms associated with the withdrawal of opiates.

MOST COMMON ADVERSE REACTIONS

The most frequently reported adverse reactions (≥25%) in clinical trials were dizziness, nausea, confusional state, and nystagmus. Slower titration of PRIALT may result in fewer serious adverse reactions and discontinuations for adverse reactions.

To report SUSPECTED ADVERSE REACTIONS, contact the FDA at 1-800-FDA-1088 or www.FDA.gov/medwatch. You may also contact Esteve Pharmaceuticals, S.A. at 1-888-306-6259 or drugsafety.us@esteve.com.

Please see accompanying Full Prescribing Information, including BOXED WARNING.

ESTEVE

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