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TerSera Therapeutics LLC Announces that the 2024 Polyanalgesic Consensus Conference (PACC) Guidelines issued updated guidance for administering PRIALT

- **PRIALT[®] (ziconotide) is the only FDA-approved, non-opioid intrathecal infusion treatment option for patients suffering from severe chronic pain for whom intrathecal therapy is warranted, and who are intolerant of or refractory to other treatments.**

DEERFIELD, IL — JULY 23, 2024 — TerSera Therapeutics LLC announced today that the 2024 Polyanalgesic Consensus Conference (PACC) guidelines reinforce the role of non-opiate PRIALT in treating severe chronic pain. The 2024 PACC guidelines build upon prior iterations. This includes the 2016 PACC guidelines which recommend PRIALT as a first line option for neuropathic (chronic pain that occur when a health condition affects the nerves that send sensations to the brain) and nociceptive pain (pain caused by damage to body tissue).¹ The updated PACC Guidelines were published in the journal of *Neuromodulation* on May 16, 2024.²

As noted in the guidelines, “proper individualized dosing is paramount for success with ziconotide.” The updated 2024 PACC guidelines discuss several crucial parameters for starting a patient successfully on PRIALT. Please refer to the full 2024 PACC Guidelines for additional information.²

“The updated 2024 PACC guidelines provide clinicians with recommendations on how to manage PRIALT therapy for patients with severe, chronic pain,” said Gladstone C. McDowell II, MD. Dr. McDowell is the founder and former Medical Director of Integrated Pain Solutions in Columbus, Ohio and an author of the PACC guidelines. “In addition, it is beneficial to have an effective non-opioid analgesic option for this patient population. I appreciate having the ability to mitigate the potential risk of dependence and addiction for patients by using PRIALT.”

Nancy Martin, MD, PharmD, Chief Medical Officer at TerSera, commented, “The PACC guidelines expert panel has continued to support PRIALT as an option for patients with severe, chronic pain who are refractory to other treatments.”

The International Neuromodulation Society (INS) commissioned a panel of distinguished clinical experts, and a series of Polyanalgesic Consensus Conferences produced the first guidelines after the inaugural meeting in 1999.² The authors of the PACC guidelines consist of an international, multidisciplinary team of experts in the intrathecal drug delivery.¹⁻²

PRIALT approved by the U.S. Food and Drug Administration (FDA) in 2004, is used to manage severe chronic pain in adults when other treatments do not work, stop working or cannot be tolerated. PRIALT is placed directly into the spinal fluid (termed “intrathecal” use) by a qualified physician who determines that the patient is appropriate for this procedure. PRIALT is not an opioid and is not a controlled, scheduled drug, meaning that the drug does not show the potential for dependence and subsequent abuse.⁴

According to the Centers for Disease Control and Prevention (CDC), it is estimated that nearly 17 million Americans suffer from severe chronic pain of some kind.³ Chronic pain conditions may be the result of more than one cause—damage to body tissues (nociceptive), damage to the nervous system (neuropathic), or a



mix of the two.¹⁻² Severe chronic pain patients are treated in a variety of ways, including use of oral opioids, transdermal opioids, physical therapy, injection therapy, spinal cord stimulation, spinal surgery, and more. When these methods do not adequately manage the individual's pain, many doctors prescribe an intrathecal infusion treatment in which a pump is surgically implanted in the abdomen to deliver pain medication directly to the spinal cord to inhibit pain signals. In addition to PRIALT, only morphine is FDA-approved as an intrathecal (IT) infusion treatment for severe chronic pain.

ABOUT TERSERA THERAPEUTICS

TerSera Therapeutics is a biopharmaceutical company with a focus in oncology, acute care, and non-opioid pain management. Founded in 2016, TerSera is building new cornerstones of care through its portfolio of unique therapeutics, amplifying their ability to deliver meaningful outcomes for patients. For more information about TerSera Therapeutics, please visit tersera.com.

ABOUT PRIALT⁴

PRIALT intrathecal solution is an N-type calcium channel antagonist used to treat severe chronic pain in patient's refractory to other treatments. PRIALT was first approved in 2004; PRIALT is available as a 1- or 5-mL vial of 100 mcg/mL solution or a 20 mL vial of 25 mcg/mL solution.

INDICATION

PRIALT is a prescription medicine used to treat severe chronic pain in adults who cannot take other treatments or when other treatments do not work, stop working, or cause bothersome side effects. PRIALT can only be delivered by or under the direction of a doctor who injects the medicine into your spinal fluid through a special device (a procedure called intrathecal infusion) and should only be used in patients who are appropriate for the procedure.

IMPORTANT SAFETY INFORMATION

PRIALT may cause serious side effects including psychiatric (mental) symptoms and problems thinking (confusion, memory problems, speech difficulties). The doctor should be called immediately if, while taking PRIALT, you are confused or disoriented, are less alert, see or hear things that are not real (hallucinations), have changes in mood or consciousness.

Your doctor may stop your treatment with PRIALT, give you other medicines, or require you to be hospitalized if you experience any of these symptoms.

You should not be given PRIALT if you:

- are allergic to PRIALT or any of its ingredients
- have a condition or are receiving a treatment that would cause an injection in your spinal fluid to be unsafe
- have or had a mental illness called psychosis (a loss of contact with reality, usually including delusions (false beliefs about what is taking place or who one is) or hallucinations (seeing or hearing things that are not real))

PRIALT may cause or worsen depression, which increases the risk of suicide. People 65 years of age and older



have a higher risk for confusion with PRIALT. Taking certain other medicines along with PRIALT may raise the risk of having problems with thinking or alertness. Tell your doctor about all the medicines you are taking.

Meningitis (inflammation of the protective membranes covering the brain and spinal cord) or other infections can happen if the infusion device becomes contaminated. Tell your doctor right away if you have fever, headache, stiff neck, changes in mental status (feeling tired, confused, disoriented), nausea, vomiting, and/or seizures as these may be symptoms of developing meningitis.

PRIALT may cause unconsciousness or reduced mental alertness. Avoid activities where you need to be alert, awake, and have full control of your body (activities like operating machinery or driving a car) during treatment with PRIALT.

Tell the doctor if you experience new or worsening muscle pain, soreness, weakness or if your urine is dark in color as this could be a sign of rare but serious muscle side effects.

You should also tell the doctor if you are pregnant, plan to become pregnant or if you are breastfeeding.

The most common side effects of PRIALT include dizziness, nausea, confusion, and uncontrolled eye movements. These are not all the possible side effects of PRIALT. Talk to your doctor about any side effects you may be experiencing.

To report suspected adverse reactions, contact the FDA at 1-800-FDA-1088 or www.FDA.gov/medwatch. You may also contact TerSera Therapeutics at 1-844-334- 4035 or medicalinformation@tersera.com.

Please see Important Safety Information above and [full Prescribing Information](#), including BOXED Warning.

References

1. Deer T.R., Pope J.E., Hayek S., Lamer T.J., Veizi I.E., Erdek M., Wallace M.S., Grider J.S., Levy R.M., Prager J., Rosen S.M., Saulino M., Yaksh T.L., De Andrés J.A., Abejon Gonzalez D., Vesper J., Schu S., Simpson B., Mekhail N. 2017. The Polyanalgesic Consensus Conference (PACC): Recommendations for Intrathecal Drug Delivery: Guidance for Improving Safety and Mitigating Risks. *Neuromodulation* 2017; E-pub ahead of print. DOI:10.1111/ner.12579
2. Deer T.R., Hayek S.M., Grider J.S., Hagedorn J.M., McDowell G.C., Kim P., Dupoirion D., Goel V., Duarte R., Pilitsis J.G., Leong M.S., De Andrés J., Perruchoud C., Sukumaran H., Abd-Elsayed A., Saulino M., Patin D., Poree L.R., Strand N., Gritsenko K., Osborn J.A., Dones I., Bux A., Shah J.M., Lindsey B.L., Shaw E., Yaksh T.L., Levy R.M. 2024. The Polyanalgesic Consensus Conference (PACC)[®]: Intrathecal Drug Delivery Guidance on Safety and Therapy Optimization When Treating Chronic Non-cancer Pain. *Neuromodulation* 2024; -:1–33.
3. Rikard, S. M., Strahan, A. E., Schmit, K. M., & Guy Jr., G. P. (2023). Chronic Pain Among Adults — United States, 2019–2021. *MMWR Morbidity and Mortality Weekly Report*, 72(15), 433–438.
4. PRIALT[®] (ziconotide). Prescribing information. TerSera Therapeutics LLC.

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