NEWS RELEASE

Assertio to Present New Data from Real-World Evidence Study of SYMPAZAN® at upcoming 150th Annual Meeting of the American Neurological Association

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- Poster presentation will feature new data for SYMPAZAN, the only FDA-approved oral film formulation of clobazam for adjunctive treatment of seizures associated with Lennox-Gastaut syndrome in patients two years of age or older
- Abstract is now available on ANA2025 website

LAKE FOREST, Ill., Sept. 10, 2025 (GLOBE NEWSWIRE) -- Assertio Holdings, Inc. (“Assertio” or the “Company”) (Nasdaq: ASRT), a pharmaceutical company with comprehensive commercial capabilities offering differentiated products designed to address patients’ needs, today announced that the company will present new data for SYMPAZAN (clobazam) Oral Film in a poster presentation at the 150th Annual Meeting of the American Neurological Association (ANA2025), September 13-16, 2025, Baltimore Marriott Waterfront, Baltimore.

The poster presentation will expand on data from an abstract titled “M266: Real-World Evidence Study of Patients with Lennox-Gastaut Syndrome Taking Clobazam Oral Soluble Film: Demographics, Medications, and Comorbidities” (**click here** for link to abstracts). The poster will be available on Monday, September 15, 2025, from 12:00 – 7:30 p.m. ET (6:00 – 7:30 p.m. presentation).

Assertio will provide more information about the study on the day of the poster’s availability, in accordance with the ANA2025 embargo policy. For additional information about the conference, please visit the ANA2025 website (click here: **https://myana.org/meetings/annual-meeting/**).

About Assertio

Assertio is a pharmaceutical company with comprehensive commercial capabilities offering differentiated products designed to address patients' needs. Our focus is on supporting patients by marketing products in oncology, neurology, and pain management. To learn more about Assertio, visit **www.assertiotx.com**.

About Lennox-Gastaut Syndrome

Lennox-Gastaut Syndrome or "LGS" is a severe epilepsy syndrome. LGS is a rare disease, affecting about 50,000 people in the United States. It is generally diagnosed between the ages of three and five, but some people aren't correctly diagnosed until much later. People with LGS may have many different types of seizures, and some people with LGS also experience cognitive and behavioral challenges. Managing LGS is challenging due to its treatment-resistant seizures and the need for individualized approaches to address evolving symptoms over a patient's lifetime.

About SYMPAZAN Oral Film

SYMPAZAN is the first and only FDA-approved oral film formulation of clobazam, a benzodiazepine approved for adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in patients two years of age or older. SYMPAZAN oral film is berry flavored and offered in 5 mg, 10 mg, and 20 mg dosages consistent with other clobazam formulations.

INDICATIONS AND USAGE

SYMPAZAN® (clobazam) oral film, CIV is indicated for the adjunctive treatment of seizures associated with Lennox-Gastaut Syndrome (LGS) in patients 2 years of age or older.

IMPORTANT SAFETY INFORMATION for SYMPAZAN

WARNING: RISKS FROM CONCOMITANT USE WITH OPIOIDS; ABUSE, MISUSE, AND ADDICTION; and DEPENDENCE AND WITHDRAWAL REACTIONS

- Concomitant use of benzodiazepines and opioids may result in profound sedation, respiratory depression, coma, and death. Reserve concomitant prescribing of these drugs for patients for whom alternative treatment options are inadequate. Limit dosages and durations to the minimum required. Follow patients for signs and symptoms of respiratory depression and sedation.
- The use of benzodiazepines, including SYMPAZAN, exposes users to risks of abuse, misuse, and addiction, which can lead to overdose or death. Before prescribing SYMPAZAN and throughout treatment, assess each patient's risk for abuse, misuse, and addiction.
- Abrupt discontinuation or rapid dosage reduction of SYMPAZAN after continued use may precipitate acute withdrawal reactions, which can be life-threatening. To reduce the risk of withdrawal reactions, use a gradual

taper to discontinue SYMPAZAN.

CONTRAINDICATIONS

SYMPAZAN is contraindicated in patients with a history of hypersensitivity to the drug or its ingredients.

WARNINGS AND PRECAUTIONS

Risks from Concomitant Use with Opioids

Observational studies have demonstrated that concomitant use of opioid analgesics and benzodiazepines increases the risk of drug-related mortality compared to use of opioids alone. If a decision is made to prescribe SYMPAZAN concomitantly with opioids, prescribe the lowest effective dosages and minimum durations of concomitant use. Advise both patients and caregivers about the risks of respiratory depression and sedation when SYMPAZAN is used with opioids.

Abuse, Misuse, and Addiction

Abuse and misuse of benzodiazepines often (but not always) involves the use of doses greater than the maximum recommended dosage and commonly involves concomitant use of other medications, alcohol, and/or illicit substances, which is associated with an increased frequency of serious adverse outcomes, including respiratory depression, overdose, or death.

Use of SYMPAZAN, particularly in patients at elevated risk, necessitates counseling about the risks and proper use of SYMPAZAN along with monitoring for signs and symptoms of abuse, misuse, and addiction. Prescribe the lowest effective dosage; avoid or minimize concomitant use of Central Nervous System (CNS) depressants and other substances associated with abuse, misuse, and addiction (e.g., opioid analgesics, stimulants); and advise patients on the proper disposal of unused drug. If a substance use disorder is suspected, evaluate the patient and institute (or refer them for) early treatment, as appropriate.

Dependence and Withdrawal Reactions

Patients at an increased risk of withdrawal reactions after benzodiazepine discontinuation or rapid dosage reduction include those who take higher dosages and those who have had longer durations of use.

The continued use of benzodiazepines, including SYMPAZAN, may lead to clinically significant physical dependence. Abrupt discontinuation or rapid dosage reduction of SYMPAZAN after continued use, or administration of flumazenil (a benzodiazepine antagonist) may precipitate acute withdrawal reactions, which can be life-threatening (e.g., seizures). In some cases, benzodiazepine users have developed protracted withdrawal syndrome with withdrawal symptoms lasting weeks to more than 12 months.

Potentiation of Sedation from Concomitant Use with Central Nervous System (CNS) Depressants SYMPAZAN has a CNS depressant effect. Caution patients and/or caregivers against simultaneous use with other CNS depressants or alcohol as the effects of other CNS depressants or alcohol may be potentiated.

Somnolence or Sedation SYMPAZAN causes dose-related somnolence and sedation, which generally begins within the first month of treatment and may diminish with continued treatment. Monitor patients for somnolence and sedation, particularly with concomitant use of other CNS depressants. Caution patients against engaging in hazardous activities requiring mental alertness, i.e., operating dangerous machinery or motor vehicles, until the effect of SYMPAZAN is known.

Serious Dermatological Reactions Serious skin reactions, including Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN), have been reported with clobazam in both children and adults. Discontinue SYMPAZAN at the first sign of rash, unless the rash is clearly not drug-related.

Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), also known as multiorgan hypersensitivity, has been reported in patients taking antiepileptic drugs, including clobazam. These events can be fatal or life-threatening, particularly if diagnosis and treatment do not occur as early as possible. DRESS typically, although not exclusively, presents with fever, rash, lymphadenopathy, and/or facial swelling, in association with other organ system involvement. Eosinophilia is often present. If such signs or symptoms are present, the patient should be evaluated immediately. SYMPAZAN should be discontinued if an alternative etiology for the signs or symptoms cannot be established.

Suicidal Behavior and Ideation Antiepileptic drugs (AEDs), including SYMPAZAN, increase the risk of suicidal thoughts or behavior in patients taking these drugs for any indication. Patients treated with any AED for any indication should be monitored for the emergence or worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior.

Neonatal Sedation and Withdrawal Syndrome Use of SYMPAZAN late in pregnancy can result in sedation (respiratory depression, lethargy, hypotonia) and/or withdrawal symptoms (hyperreflexia, irritability, restlessness, tremors, inconsolable crying, and feeding difficulties) in the neonate. Monitor neonates exposed to SYMPAZAN during pregnancy or labor for signs of sedation and monitor neonates exposed to SYMPAZAN during pregnancy for signs of withdrawal; manage these neonates accordingly.

ADVERSE REACTIONS
Adverse reactions (≥10% and more frequently than placebo) included constipation, somnolence or sedation, pyrexia, lethargy, and drooling.

DRUG INTERACTIONS

Opioids: The concomitant use of benzodiazepines and opioids increases the risk of respiratory depression. Limit dosage and duration of concomitant use of benzodiazepines and opioids and follow patients closely for respiratory depression and sedation.

CNS Depressants and Alcohol: Concomitant use of SYMPAZAN with other CNS depressants, including alcohol, may increase the risk of sedation and somnolence. Caution patients and/or caregivers against simultaneous use with other CNS depressants or alcohol, as effects of other CNS depressants or alcohol may be potentiated.

Hormonal Contraceptives: Hormonal contraceptives that are metabolized by CYP3A4: Effectiveness may be diminished when given with SYMPAZAN. Additional non-hormonal forms of contraception are recommended when using SYMPAZAN.

Drug Metabolized by CYP2D6: SYMPAZAN inhibits CYP2D6, therefore dose adjustment may be necessary of drugs metabolized by CYP2D6 when co-administered with SYMPAZAN.

Strong and Moderate Inhibitors of CYP2C19. Dosage adjustment of SYMPAZAN may be necessary when co-administered with strong CYP2C19 inhibitors (e.g., fluconazole, fluvoxamine, ticlopidine) or moderate CYP2C19 inhibitors (e.g., omeprazole).

Cannabidiol: Coadministration of cannabidiol and SYMPAZAN may increase the risk of SYMPAZAN-related adverse reactions. Consider dose reduction of cannabidiol or SYMPAZAN should this occur.

USE IN SPECIFIC POPULATIONS

Pregnancy: Published data from observational studies on the use of benzodiazepines during pregnancy do not report a clear association with benzodiazepines and major birth defects. Neonates born to mothers using benzodiazepines late in pregnancy have been reported to experience symptoms of sedation and/or neonatal withdrawal. Benzodiazepines cross the placenta and may produce respiratory depression, hypotonia, and sedation in neonates. Monitor neonates exposed to SYMPAZAN during pregnancy or labor for signs of sedation, respiratory depression, hypotonia, feeding problems, or signs of withdrawal. Manage these neonates accordingly. Encourage pregnant women taking SYMPAZAN to call the toll-free number 1-888-233-2334 to enroll in the Pregnancy Registry or visit **https://www.aedpregnancyregistry.org/**

Lactation: SYMPAZAN is excreted in human milk. There are reports of sedation, poor feeding and poor weight gain in infants exposed to benzodiazepines through breast milk. Infants exposed to SYMPAZAN should be monitored for these effects. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for SYMPAZAN® and any potential adverse effects on the breastfed infant from SYMPAZAN® or from the underlying maternal condition.

OVERDOSAGE

Overdosage of benzodiazepines is characterized by central nervous system depression ranging from drowsiness to coma. In severe overdosage cases, patients may develop respiratory depression and coma. Overdosage of benzodiazepines in combination with other CNS depressants (including alcohol and opioids) may be fatal. Employ general supportive measures, including intravenous fluids and airway maintenance for overdosage management. Flumzenil, a specific benzodiazepine receptor antagonist, can lead to withdrawal and adverse reactions, including seizures. The risk of withdrawal seizures with flumazenil use may be increased in patients with epilepsy. Flumazenil is contraindicated in patients who have received a benzodiazepine for control of a potentially life-threatening condition (e.g., status epilepticus). See the flumazenil injection Prescribing Information. Consider contacting the Poison Help line (1-800-222-1222) or a medical toxicologist for additional overdosage management recommendations.

Please see Full Prescribing Information, including BOXED WARNING and Patient Information at **https://www.sympazan.com/pdfs/pi.pdf**

To report SUSPECTED ADVERSE REACTIONS, contact Assertio at 1-800-518-1084 or FDA at 1-800-FDA-1088 or **www.fda.gov/medwatch**.

Forward-Looking Statements

Statements in this communication that are not historical facts are forward-looking statements that reflect Assertio's current expectations, assumptions and estimates of future performance and economic conditions. These forward-looking statements are made in reliance on the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These forward-looking statements relate to, among other things, future events or the future performance or operations of Assertio, including risks related to our ability to realize the benefits from our operating model, deliver or execute on our business strategy, including to expand or diversify our asset base and market reach and drive cash flows and growth, successfully integrate new assets, and explore new business development initiatives. All statements other than historical facts may be forward-looking statements and can be identified by words such as "anticipate," "believe," "could," "design," "estimate," "expect," "forecast," "goal," "guidance," "imply," "intend," "may," "objective," "opportunity," "outlook," "plan," "position," "potential," "predict," "project," "prospective," "pursue," "seek," "should," "strategy," "target," "would," "will," "aim" or other similar expressions that convey the uncertainty of future events or outcomes and are used to identify forward-looking statements. Such forward-looking statements are not guarantees of future performance and are subject to risks, uncertainties and other factors, some of which are beyond the control of Assertio, including the risks described in Assertio's Annual Report on Form 10-K and Quarterly Reports on Form 10-Q filed with the U.S. Securities and Exchange Commission ("SEC") and in other filings Assertio makes with the SEC from time to time.

Investors and potential investors are urged not to place undue reliance on forward-looking statements in this communication, which speak only as of this date. While Assertio may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to update or revise any forward-looking-statements contained in this press release whether as a result of new information or future events, except as may be required by applicable law.

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