# Assertio Holdings, Inc. Partners with Cove, a Leading Migraine Telemedicine Platform, To Launch Direct to Patient Digital Campaign to Increase Accessibility of CAMBIA® (diclofenac potassium) and SPRIX® (ketorolac tromethamine)

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**Collaboration will Increase Access to CAMBIA and SPRIX through Cove's Innovative, and Continuous Online Physician Care**

LAKE FOREST, Ill. and NEW YORK, May 05, 2021 (GLOBE NEWSWIRE) -- Assertio Holdings, Inc. ("Assertio" or "the Company") (NASDAQ: ASRT), and Cove, a leading migraine telemedicine platform, today announced a collaboration to make CAMBIA (diclofenac potassium) for oral solution and SPRIX (ketorolac tromethamine) nasal spray available to Cove's patient population. This collaboration will make it easier for more patients to gain access to high-quality physician care.

Using Cove's online telemedicine platform, patients complete a consultation with a licensed physician who can prescribe a variety of treatment options, including CAMBIA for a patient's acute treatment of migraine attacks with or without aura in adults and SPRIX for short-term (up to 5 days) management of moderate to moderately severe pain which requires analgesia at the opioid level in adults.

"We are thrilled to be working with Assertio to provide CAMBIA and SPRIX as options to the appropriate patients," said Caroline Hofmann, General Manager of Cove. "We know that patients need more options to treat their conditions and convenient access to quality care."

"Partnering with Cove, a leading telemedicine platform, furthers our strategy by enhancing our foundational digital platform and virtual engagement efforts to better serve our patients," said Dan Peisert, President and Chief Executive Officer of Assertio. "This is an exciting direct to patient model for those who prefer a convenient, digital telemedicine option."

**CAMBIA and SPRIX each belong to a class of medications called non-steroidal anti-inflammatory drugs (NSAIDs) and have a Boxed Warning for serious cardiovascular and gastrointestinal events. Please see the indications and Important Safety Information below.**

**CAMBIA INDICATIONS AND USAGE**

CAMBIA® (diclofenac potassium) for oral solution is indicated for the acute treatment of migraine attacks with or without aura in adults (18 years of age or older).

Limitations of Use:
- CAMBIA is not indicated for the prophylactic therapy of migraine.
- The safety and effectiveness of CAMBIA have not been established for cluster headache.

**SPRIX INDICATIONS AND USAGE**

SPRIX® (ketorolac tromethamine) is indicated in adult patients for the short term (up to 5 days) management of moderate to moderately severe pain that requires analgesia at the opioid level.

Limitations of Use
- SPRIX is not for use in pediatric patients less than 2 years of age.

**CAMBIA IMPORTANT SAFETY INFORMATION**

**WARNING: RISK OF SERIOUS CARDIOVASCULAR AND GASTROINTESTINAL EVENTS**
**Cardiovascular Thrombotic Events**
**• Non-steroidal anti-inflammatory drugs (NSAIDs) cause an increased risk of serious cardiovascular thrombotic events, including myocardial infarction, and stroke, which can be fatal. This risk may occur early in treatment and may increase with duration of use.**
**• CAMBIA is contraindicated in the setting of coronary artery bypass graft (CABG) surgery.**
**Gastrointestinal Bleeding, Ulceration, and Perforation**
**• NSAIDs cause an increased risk of serious gastrointestinal (GI) adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients and patients with a prior history of peptic ulcer disease and/or GI bleeding are at greater risk for serious GI events.**

**Use the lowest effective dosage for the shortest duration consistent with individual patient treatment goals.** The safety and effectiveness of a second dose have not been established. Different formulations of oral diclofenac (e.g., CAMBIA, diclofenac sodium enteric-coated tablets, diclofenac sodium

extended-release tablets, or diclofenac potassium immediate-release tablets) may not be bioequivalent even if the milligram strength is the same. Therefore, it is not possible to convert dosing from any other formulation of diclofenac to CAMBIA.

**CONTRAINDICATIONS**

CAMBIA is contraindicated in the following patients:

- Known hypersensitivity (e.g., anaphylactic reactions and serious skin reactions) to diclofenac or any components of the drug product.
- History of asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs. Severe, sometimes fatal, anaphylactic reactions to NSAIDs have been reported in such patients.
- In the setting of coronary artery bypass graft (CABG) surgery.

**WARNINGS AND PRECAUTIONS**

Hepatotoxicity: Elevations of one or more liver tests may occur during therapy with CAMBIA. Postmarketing surveillance has reported cases of severe hepatic reactions, including liver necrosis, jaundice, fulminant hepatitis with and without jaundice, and liver failure. Some of these reported cases resulted in fatalities or liver transplantation. Inform patients of warning signs and symptoms of hepatotoxicity. Discontinue if abnormal liver tests persist or worsen or if clinical signs and symptoms of liver disease develop.

Hypertension: NSAIDs, including CAMBIA, can lead to new onset of hypertension or worsening of preexisting Hypertension. Patients taking some antihypertensive medications may have impaired response to these therapies when taking NSAIDs. Monitor blood pressure.

Heart Failure and Edema: Avoid use of CAMBIA in patients with severe heart failure unless benefits are expected to outweigh risk of worsening heart failure. If CAMBIA is used in patients with severe heart failure, monitor patients for signs of worsening heart failure.

Renal Toxicity and Hyperkalemia: Long-term administration of NSAIDs has resulted in renal papillary necrosis and other renal injury. Renal toxicity has also been seen in patients in whom renal prostaglandins have a compensatory role in the maintenance of renal perfusion. In these patients, administration of an NSAID may cause a dose-dependent reduction in prostaglandin formation and, secondarily, in renal blood flow, which may precipitate overt renal decompensation. Monitor renal function in patients with renal or hepatic impairment, heart failure, dehydration, or hypovolemia. Avoid use of CAMBIA in patients with advanced renal disease unless benefits are expected to outweigh risk of worsening renal function. Increases in serum potassium concentration, including hyperkalemia, have been reported with use of NSAIDs, even in some patients without renal impairment.

Anaphylactic Reactions: Seek emergency help if an anaphylactic reaction occurs.

Exacerbation of Asthma Related to Aspirin Sensitivity: CAMBIA is contraindicated in patients with aspirin sensitive asthma. Monitor patients with preexisting asthma (without aspirin sensitivity).

Serious Skin Reactions: NSAIDs, including diclofenac, can cause serious skin adverse reactions which can be fatal. Discontinue CAMBIA at first appearance of skin rash or other signs of hypersensitivity.

Medication Overuse Headache: Detoxification may be necessary.

Premature Closure of Fetal Ductus Arteriosus: Avoid use in pregnant women starting at 30 weeks gestation.

Hematologic Toxicity: Monitor hemoglobin or hematocrit in patients with any signs or symptoms of anemia.

**ADVERSE REACTIONS**

The most common adverse events (≥1% and greater than placebo) in clinical trials with CAMBIA were nausea and dizziness.

**DRUG INTERACTIONS**

Drugs That Interfere with Hemostasis (e.g. warfarin, aspirin, SSRIs/SNRIs): Increased risk of serious bleeding with use of anticoagulants, antiplatelet agents, selective serotonin reuptake inhibitors (SSRIs), and serotonin norepinephrine reuptake inhibitors (SNRIs). Monitor patients for bleeding who are concomitantly taking CAMBIA with drugs that interfere with hemostasis. Concomitant use of CAMBIA and analgesic doses of aspirin is not generally recommended.

ACE Inhibitors and ARBs: Concomitant use with CAMBIA in elderly, volume depleted, or those with renal impairment may result in deterioration of renal function. In such high risk patients, monitor for signs of worsening renal function.

Diuretics: NSAIDs can reduce natriuretic effect of loop and thiazide diuretics. Monitor patients to assure diuretic efficacy including antihypertensive effects.

Digoxin: Concomitant use with CAMBIA can increase serum concentration and prolong half-life of digoxin. Monitor serum digoxin levels.

Inhibitors of Cytochrome P450 2C9: Diclofenac is metabolized predominantly by Cytochrome P-450 CYP2C9. During concomitant use of CAMBIA and drugs that inhibit CYP2C9, an increase in the duration between CAMBIA doses for subsequent migraine attacks may be necessary.

**USE IN SPECIFIC POPULATIONS**

Pregnancy: Use of NSAIDs during the third trimester of pregnancy increases the risk of premature closure of the fetal ductus arteriosus. Avoid use of NSAIDs in pregnant women starting at 30 weeks gestation.

Infertility: NSAIDs are associated with reversible infertility. Consider withdrawal of CAMBIA in women who have difficulties conceiving.

**Please see full Prescribing Information on CAMBIA.com, including BOXED WARNING and MEDICATION GUIDE.**
**To report SUSPECTED ADVERSE REACTIONS, contact Assertio Therapeutics, Inc.**
**at 1-866-458-6389 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.**

**SPRIX IMPORTANT SAFETY INFORMATION**

**WARNING: RISK OF SERIOUS CARDIOVASCULAR AND GASTROINTESTINAL EVENTS**

**Cardiovascular Thrombotic Events**

**• Nonsteroidal anti-inflammatory drugs (NSAIDS) cause an increased risk of serious cardiovascular thrombotic events, including myocardial infarction and stroke, which can be fatal. This risk may occur early in treatment and may increase with duration of use.**

**• SPRIX® is contraindicated in the setting of coronary artery bypass graft (CABG) surgery.**

**Gastrointestinal Bleeding, Ulceration, and Perforation**

**• NSAIDS cause an increased risk of serious gastrointestinal (GI) adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients and patients with a prior history of peptic ulcer disease and/or GI bleeding are at greater risk for serious GI events.**

**Use SPRIX at the lowest effective dosage for shortest duration consistent with individual patient treatment goals.**

**CONTRAINDICATIONS**

SPRIX is contraindicated in the following patients:

• Known hypersensitivity to ketorolac or any components of the drug product.

• History of asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs. Severe, sometimes fatal, anaphylactic reactions to NSAIDs have been reported in such patients.

• In the setting of coronary artery bypass graft (CABG) surgery.

• Use in patients with active peptic ulcer disease or with recent gastrointestinal bleeding or perforation.

• Use as a prophylactic analgesic before any major surgery.

• Use in patients with advanced renal disease or patients at risk for renal failure due to volume depletion.

• Use in labor and delivery. May adversely affect fetal circulation and inhibit uterine contractions, thus increasing the risk of uterine hemorrhage.

• Use in patients with suspected or confirmed cerebrovascular bleeding, hemorrhagic diathesis, incomplete hemostasis, or those for whom hemostasis is critical.

• Concomitant use with probenecid or pentoxifylline.

**WARNINGS AND PRECAUTIONS**

Hepatotoxicity: Elevations of ALT or AST have been reported in patients with NSAIDs. In addition, rare, sometimes fatal, cases of severe hepatic injury, including fulminant hepatitis, liver necrosis, and hepatic failure have been reported. Inform patients of warning signs and symptoms of hepatotoxicity. Discontinue immediately if abnormal liver tests persist or worsen or if clinical signs and symptoms of liver disease develop.

Hypertension: NSAIDs, including SPRIX, can lead to new onset or worsening of preexisting hypertension. Patients taking some antihypertensive medications may have impaired response to these therapies when taking NSAIDs. Monitor blood pressure.

Heart Failure and Edema: Avoid use of SPRIX in patients with severe heart failure unless benefits are expected to outweigh risk of worsening heart failure. If SPRIX is used in patients with severe heart failure, monitor patients for signs of worsening heart failure.

Renal Toxicity and Hyperkalemia: Long-term administration of NSAIDs has resulted in renal papillary necrosis and other renal injury and may cause a dose-dependent reduction in prostaglandin formation, which may precipitate overt renal decompensation. Monitor renal function in patients with renal or hepatic impairment, heart failure, dehydration, or hypovolemia. Avoid use of SPRIX in patients with advanced renal disease unless benefits are expected to outweigh risk of worsening renal function.

Anaphylactic Reactions: Seek emergency help if an anaphylactic reaction occurs.

Exacerbation of Asthma Related to Aspirin Sensitivity: SPRIX is contraindicated in patients with aspirin-sensitive asthma. Monitor patients with preexisting asthma (without known aspirin sensitivity).

Serious Skin Reactions: NSAIDs, including SPRIX, can cause serious skin adverse reactions, which can be fatal. These serious events may occur without warning. Discontinue SPRIX at the first appearance of skin rash or any other sign of hypersensitivity.

Premature Closure of Fetal Ductus Arteriosus: Avoid use in pregnant women starting at 30 weeks gestation.

Hematologic Toxicity: Anemia has occurred in patients treated with NSAIDs. Monitor hemoglobin or hematocrit in patients with any signs or symptoms of anemia. Do not use SPRIX in patients for whom hemostasis is critical.

Limitations of Use: The total duration of use of SPRIX alone or sequentially with other forms of ketorolac is not to exceed 5 days. SPRIX should not be used concomitantly with other forms of ketorolac, aspirin, or other NSAIDs.

**ADVERSE REACTIONS**

The most common adverse reactions (incidence ≥2%) in patients treated with SPRIX and occurring at a rate at least twice that with placebo include: nasal discomfort; rhinalgia; increased

lacrimation; throat irritation; oliguria; rash; bradycardia; decreased urine output; increased ALT and/or AST; hypertension; rhinitis.

**DRUG INTERACTIONS**
Drugs That Interfere With Hemostasis: increased risk of serious bleeding with use of anticoagulants, antiplatelet agents, selective serotonin reuptake inhibitors (SSRIs), and serotonin norepinephrine reuptake inhibitors (SNRIs); concomitant use with pentoxifylline is contraindicated. Monitor patients for bleeding who are concomitantly taking SPRIX with drugs that interfere with hemostasis.
ACE Inhibitors, Angiotensin Receptor Blockers (ARBs), and Beta-Blockers: may diminish the antihypertensive effect of these drugs; monitor blood pressure.
ACE Inhibitors and ARBs: In elderly, volume depleted, or those with renal impairment may result in deterioration of renal function; monitor for signs of worsening renal function.
Diuretics: reduces the natriuretic effect of loop diuretics (e.g., furosemide) and thiazide diuretics in some patients. During concomitant use of SPRIX with diuretics look for signs of worsening renal function and assure diuretic efficacy and antihypertensive effects.
Digoxin: has been reported to increase the serum concentration and prolong the half-life of digoxin, monitor serum digoxin levels.

**USE IN SPECIFIC POPULATIONS**
Pregnancy: Use of NSAIDs during the third trimester of pregnancy increases the risk of premature closure of the fetal ductus arteriosus. Avoid use of NSAIDs in pregnant women starting at 30 weeks gestation.
Infertility: NSAIDs are associated with reversible infertility. Consider withdrawal of SPRIX in women who have difficulties conceiving.

**Please see full Prescribing Information on SPRIX.com, including BOXED WARNING and MEDICATION GUIDE.**
**To report SUSPECTED ADVERSE REACTIONS, contact Assertio Therapeutics, Inc. at 866-458-6389 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.**

**About Cove**

Cove is a specialized healthcare company that offers personalized treatment solutions. Cove aims to empower patients by providing direct access to high-quality, affordable care, personalized to each customer and their specific needs. In addition to CAMBIA and SPRIX, Cove offers 20+ acute and preventative treatments. For more information, visit www.withcove.com.

**About Assertio Holdings**

Assertio is a leading commercial pharmaceutical company bringing differentiated products to patients. The Company has a robust portfolio of branded prescription products in neurology, hospital, and pain and inflammation. Assertio has grown through business development including licensing, mergers, and acquisitions. To learn more about Assertio, visit www.assertiotx.com.

**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 (the "Securities Act"), 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. All statements other than historical facts may be forward-looking statements; 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 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. These risks are more fully described in Assertio's public filings with the Securities and Exchange Commission, including Assertio's most recent annual report on Form 10-K and Quarterly Reports on Form 10-Q filed with the SEC and in other filings Assertio makes with the SEC from time to time. 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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