Rosemont Pharmaceuticals licenses Fidelity Biopharma's ONTRALFY™ (tizanidine oral solution) for adult spasticity

Rosemont Pharmaceuticals License Agreement with Fidelity Biopharma to Market ONTRALFY™ (tizanidine oral solution) for Treatment of Spasticity in Adults.

GREENVILLE, SC, UNITED STATES, January 21, 2026 /EINPresswire.com/ -- Rosemont Pharmaceuticals Announces License Agreement with Fidelity Biopharma to Market ONTRALFY™ (tizanidine oral solution) for Treatment of Spasticity in Adults.

Product will be available nationwide in February

Rosemont Pharmaceuticals has announced a license agreement with Fidelity BioPharma Company to market ONTRALFY™ (tizanidine oral solution 2 mg/5 mL) in the United States. Product will be available nationwide in February.

ONTRALFY is the first FDA approved oral solution of tizanidine, a central alpha-2-adrenergic agonist indicated for the treatment of spasticity in adults.1

ONTRALFY presumably reduces spasticity by increasing presynaptic inhibition of motor neurons. The overall effect of these actions is thought to reduce facilitation of spinal motor neurons. It is typically prescribed when spasticity interferes with daily life.

About 12 million patients suffer from spasticity worldwide.2 In patients whose spasticity is related to neurological conditions, such as stroke, spinal cord injury, multiple sclerosis, and Parkinson's disease, among others, the prevalence of swallowing difficulties is increased.3,4,5 As an oral solution, ONTRALFY provides an effective and precise dosing option for these patients.

"The licensing of ONTRALFY allows Rosemont Pharmaceuticals to continue our mission of providing alternative dosage form medicines in a variety of therapeutic areas," said John Denman, Vice President US Business Unit at Rosemont Pharmaceuticals. "ONTRALFY delivers an effective treatment option for muscle spasticity, now in a form that makes it accessible to patients who might not have been able to take it as a tablet or capsule."

For further information, including full prescribing information and safety profile, please visit www.ontralfy.com.

IMPORTANT SAFETY INFORMATION

ONTRALFY™ (tizanidine oral solution)

INDICATIONS AND USAGE

ONTRALFY™ is a central alpha-2-adrenergic agonist indicated for the treatment of spasticity in adults. (1)

CONTRAINDICATIONS

ONTRALFY is contraindicated in patients:
- taking strong CYP1A2 inhibitors [see Drug Interactions (7.1)]
- with a history of hypersensitivity to tizanidine or the ingredients in ONTRALFY. Symptoms have included anaphylaxis and angioedema [see Warnings and Precautions (5.5)]

WARNINGS AND PRECAUTIONS

Hypotension

ONTRALFY is an α2-adrenergic agonist that can produce hypotension [see Adverse Reactions (6.1) and Drug Interactions (7.5)]. Syncope has been reported in patients treated with tizanidine in the postmarketing setting. The risk of hypotension may be minimized by dose titration; monitoring for signs and symptoms of hypotension prior to dosage increase may minimize the risks associated with hypotension. In addition, patients moving from a supine to fixed upright position may be at increased risk for hypotension and orthostatic effects.

Monitor for hypotension when ONTRALFY is used in patients receiving concurrent antihypertensive therapy. It is not recommended that ONTRALFY be used with other α2-adrenergic agonists. Clinically significant hypotension (decreases in both systolic and diastolic pressure) has been reported with concomitant administration of tizanidine and strong CYP1A2 inhibitors [see Clinical Pharmacology (12.3)]. Therefore, concomitant use of ONTRALFY with strong CYP1A2 inhibitors is contraindicated [see Contraindications (4) and Drug Interactions (7.1)]. (5.1)

Liver Injury

ONTRALFY may cause hepatocellular liver injury. Liver function test abnormality and hepatotoxicity have been observed with tizanidine, the active moiety of ONTRALFY [see Adverse Reactions (6.1, 6.2)]. Monitoring of aminotransferase levels is recommended at baseline and 1 month after maximum dose is achieved, or if hepatic injury is suspected [see Dosage and

Administration (2.1) and Use in Specific Populations (8.7)]. (5.2)

Sedation

ONTRALFY can cause sedation, which may interfere with everyday activity. In the multiple dose studies of tizanidine, the prevalence of patients with sedation peaked following the first week of titration and then remained stable for the duration of the maintenance phase of the study [see Adverse Reactions (6.1)]. The CNS depressant effects of ONTRALFY with alcohol and other CNS depressants (e.g., benzodiazepines, opioids, tricyclic antidepressants) may be additive [see Drug Interactions (7.4)]. Monitor patients who take ONTRALFY with another CNS depressant for symptoms of excess sedation. (5.3)

Hallucinosis/Psychotic-Like Symptoms

Tizanidine use has been associated with hallucinations. Formed, visual hallucinations or delusions were reported in 5 of 170 patients (3%) in two North American controlled clinical studies of tizanidine. Most of the patients were aware that the events were unreal. One patient developed psychosis in association with the hallucinations. One patient among these 5 continued to have problems for at least 2 weeks following discontinuation of tizanidine. Hallucinations have also been reported with tizanidine use in the postmarketing setting. Consider discontinuing ONTRALFY in patients who develop hallucinations. (5.4)

Hypersensitivity Reactions

ONTRALFY can cause anaphylaxis. Signs and symptoms of hypersensitivity, including respiratory compromise, urticaria, and angioedema of the throat and tongue, have been reported. ONTRALFY is contraindicated in patients with a history of hypersensitivity reactions to tizanidine [see Contraindications (4)]. (5.5)

Withdrawal Adverse Reactions

ONTRALFY can cause withdrawal adverse reactions, which include rebound hypertension, tachycardia, and hypertonia. To minimize the risk of these reactions, particularly in patients who have been receiving high doses of ONTRALFY (20 to 28 mg daily) for long periods of time (9 weeks or more) or who may be on concomitant treatment with narcotics, the ONTRALFY dosage should be decreased slowly [see Dosage and Administration (2.5)]. (5.6)

ADVERSE REACTIONS

The most common adverse reactions (in greater than 10% of patients taking tizanidine) were dry mouth, somnolence/sedation, asthenia (weakness, fatigue and/or tiredness), and dizziness. (6.1)

DRUG INTERACTIONS

Strong CYP1A2 Inhibitors

Concomitant use of ONTRALFY with strong cytochrome P450 1A2 (CYP1A2) inhibitors (e.g., fluvoxamine, ciprofloxacin) is contraindicated. Changes in pharmacokinetics of tizanidine when administered with a strong CYP1A2 inhibitor resulted in significantly decreased blood pressure, increased drowsiness, and increased psychomotor impairment [see Contraindications (4) and Clinical Pharmacology (12.3)]. (7.1)

Moderate or Weak CYP1A2 Inhibitors

Concomitant use of ONTRALFY with moderate or weak CYP1A2 inhibitors (e.g., zileuton, antiarrhythmics [amiodarone, mexiletine, propafenone, and verapamil], cimetidine, famotidine, oral contraceptives, acyclovir, and ticlopidine) should be avoided. If concomitant use is clinically necessary, and adverse reactions such as hypotension, bradycardia, or excessive drowsiness occur, reduce ONTRALFY dosage or discontinue ONTRALFY therapy [see Clinical Pharmacology (12.3)]. (7.2)

Oral Contraceptives

Concomitant use of ONTRALFY with oral contraceptives is not recommended. However, if concomitant use is clinically necessary and adverse reactions such as hypotension, bradycardia, or excessive drowsiness occur, reduce or discontinue ONTRALFY therapy [see Clinical Pharmacology (12.3)]. (7.3)

Alcohol and Other CNS Depressants

Alcohol increases the exposure of tizanidine after administration of ONTRALFY. This was associated with an increase in adverse reactions of tizanidine.

Concomitant use of ONTRALFY with CNS depressants (e.g., alcohol, benzodiazepines, opioids, tricyclic antidepressants) may cause additive CNS depressant effects, including sedation. Monitor patients who take ONTRALFY with another CNS depressant for symptoms of excess sedation [see Clinical Pharmacology (12.3)]. (7.4)

α2-Adrenergic Agonists

Concomitant use of ONTRALFY with other α2-adrenergic agonists is not recommended because hypotensive effects may be cumulative [see Warnings and Precautions (5.1)]. (7.5)

Antihypertensive Medications

Concomitant use of ONTRALFY with antihypertensive medications may cause additive hypotensive effects [see Warnings and Precautions (5.1)]. Monitor patients who take ONTRALFY with antihypertensive medications for hypotension. (7.6)

USE IN SPECIFIC POPULATIONS

See Full Prescribing Information for use in specific populations and other Important Safety Information.

This Important Safety Information does not include all the information needed to use ONTRALFY safely and effectively. For more information, including full prescribing information, please visit www.ontralfy.com.

To report SUSPECTED ADVERSE REACTIONS, contact Rosemont Pharmaceuticals, LLC at 1-844-638-2235 or FDA at 1-800-FDA-1088 or www.fda.gov/MedWatch

About Rosemont Pharmaceuticals
Rosemont Pharmaceuticals is a global pharmaceutical company specialized in the development and commercialization of alternative dosage forms. Rosemont was founded more than 50 years ago and sells over 130 liquid products in more than 27 markets.

About Fidelity BioPharma
Fidelity BioPharma is a pharmaceutical company focusing on and committed to bringing the innovated finished dosage formulation, medical device and medically functional nutraceuticals, with the highest level of quality, to global consumers. Fidelity aspires to contribute to the healthcare industry through the right partnerships and the right products.

References
1. Prescribing Information PI-TIZ-01-001. Rosemont Pharmaceuticals, LLC; 2025.
2. https://www.researchandmarkets.com/reports/6102503/spasticity-epidemiology-forecast
3. https://www.mdsabstracts.org/abstract/prevalence-of-oropharyngeal-dysphagia-in-hereditary-spastic-paraplegias/
4. https://www.numberanalytics.com/blog/dysphagia-prevalence-comprehensive-review
5. https://www.aapmr.org/docs/default-source/default-document-library/aapmr-spasticity-summit-background-paper_final_branded.pdf?sfvrsn=3ce7317c_0

RMT-ONT-PR-001 1/2026

Wade Harper, Vice President, Commercial Officer
Sabal Therapeutics, LLC
+1 762-847-0428 ext. 127
email us here