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Press Release

**Averitas Pharma Announces FDA Acceptance of sNDA Filing for QUTENZA® (capsaicin) 8% Patch for the Treatment of Neuropathic Pain Associated with Diabetic Peripheral Neuropathy**

- **PDUFA date set for July 19, 2020**
- **If approved, QUTENZA would be the first topical treatment with a TRPV1 agonist indicated for the treatment of neuropathic pain associated with diabetic peripheral neuropathy.**

MORRISTOWN, N.J.--(BUSINESS WIRE)--December 18, 2019—Averitas Pharma, Inc., a subsidiary of GRT US Holding, Inc. and member of the Grünenthal Group, announced today that the supplemental New Drug Application (sNDA) for QUTENZA for the treatment of neuropathic pain associated with diabetic peripheral neuropathy has been accepted for review by the U.S. Food and Drug Administration (FDA). The FDA has set a goal date under the Prescription Drug User Fee Act (PDUFA) of July 19, 2020.

“This is a great step forward for Averitas and moves us closer towards our goal of getting QUTENZA FDA approved for this indication,” says Gabriel Baertschi, CEO Grünenthal. “There are millions of patients with painful diabetic peripheral neuropathy who have so far struggled to find effective pain relief. Offering solutions for these patients’ unmet needs is fully in line with our vision of working towards a world free of pain.”

**About neuropathic pain associated with Diabetic Peripheral Neuropathy**

Diabetes is a group of diseases marked by high levels of blood glucose resulting from defects in insulin production, insulin action or both. According to the American Diabetes Association, in 2015, 30.3 million Americans, or 9.4% of the population, had diabetes.[1] Diabetic neuropathies are the most prevalent chronic complications of diabetes.[2] Long-standing peripheral neuropathic pain associated with peripheral neuropathy occurs in one of six diabetic subjects.[3] Painful diabetic neuropathy is pain arising as a direct consequence of abnormalities of the somatosensory system in diabetic patients and predominantly affects the feet and legs.[4] People with diabetes can develop nerve problems at any time, but risk rises with age, duration of diabetes, glucose control and presence of diabetic retinopathy.[5]

**About QUTENZA**

QUTENZA is approved in the US for the management of neuropathic pain associated with postherpetic neuralgia. A single, 1-hour, local topical treatment with QUTENZA to the intact skin may provide up to 3 months of pain relief from post-shingles nerve pain (PHN) and may be repeated every 90 days or as warranted by the return of pain (not more frequently than every three months). QUTENZA delivers high concentrations of the TRPV1 agonist, capsaicin through the skin, directly to the damaged nerves that are the source of neuropathic pain. The spontaneous activity of the

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TRPV1 sensitive nerves decreases and consequently also the neuropathic pain intensity. Important safety information can be found here: www.qutenza.com

**Indication:**

QUTENZA is indicated for the management of neuropathic pain associated with postherpetic neuralgia.

**IMPORTANT SAFETY INFORMATION:**
Only physicians or healthcare professionals under the close supervision of a physician are to administer QUTENZA.

**Contraindications:**
None

**Warnings and Precautions:**
•Do not apply QUTENZA to the face or scalp to avoid risk of exposure to the eyes or mucous membranes.
•Aerosolization of capsaicin can occur and inhalation may result in coughing or sneezing.
•If skin not intended to be treated comes into contact with QUTENZA, clean area using Cleansing Gel.
•Patients may experience substantial procedural pain. Prepare to treat pain with local cooling (such as a cold pack) and/or appropriate analgesic medication.
•Transient increases in blood pressure may occur during and shortly after the QUTENZA treatment. Blood pressure changes were associated with treatment-related increases in pain. Monitor blood pressure and provide adequate support for treatment-related pain. Patients with unstable or poorly controlled hypertension or a recent history of cardiovascular or cerebrovascular events may be at an increased risk of adverse cardiovascular effects. Consider these factors prior to initiating QUTENZA treatment.
•If opioids are used to treat pain associated with the application procedure, please note that opioid treatment may affect the patient's ability to perform potentially hazardous activities such as driving or operating heavy machinery.

**Adverse Reactions:**
In clinical trials, serious adverse reactions included application associated pain and increase in blood pressure. The most common adverse reactions (≥ 5% and greater than control) were application-site erythema, application-site pain, application-site pruritus, or application-site papules, and nausea.
To report an adverse event, you can visit www.fda.gov/medwatch or call 1-800-FDA-1088; or you can call Averitas Pharma, Inc. at 1-877-900-6479.

Please click here for full Prescribing Information

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**About Averitas Pharma, Inc.**
Averitas Pharma is a revenue-generating, specialty pharmaceutical company dedicated to delivering innovative, effective, non-opioid pain management options to patients in the US. The company was formed in 2018, as a subsidiary of GRT US Holding, Inc. and member of the Grünenthal Group.

**About Grünenthal**
Grünenthal is a global leader in pain management and related diseases. As a science-based, privately-owned pharmaceutical organization, we have a long track record of bringing innovative treatments and state-of-the-art technologies to patients worldwide. Our purpose is to change lives for the better – and innovation is our passion. We are focussing all of our activities and efforts on working towards our vision of a world free of pain.
Grünenthal is headquartered in Aachen, Germany, and has affiliates in 30 countries across Europe, Latin America and the US. Our products are available in more than 100 countries. In 2018, Grünenthal employed around 4,900 people and achieved sales of € 1.3 bn.

More information: www.grunenthal.com
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