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FOR IMMEDIATE RELEASE

UPSHER-SMITH LABORATORIES LAUNCHES TOSYMRA™ (SUMATRIPTAN) NASAL SPRAY FOR THE ACUTE TREATMENT OF MIGRAINE IN ADULTS

Delivers the Efficacy of an Injectable with the Convenience of a Nasal Spray

Maple Grove, MN – October 2, 2019 – Upsher-Smith Laboratories, LLC (Upsher-Smith) today announced the launch of Tosymra™ (sumatriptan) Nasal Spray, 10 mg for the acute treatment of migraine with or without aura in adults. Tosymra is a fast-acting, easy-to-use acute migraine treatment option that delivers the efficacy of an injectable in a convenient nasal spray.

Tosymra, which was approved by the U.S. Food and Drug Administration in early 2019, was recently acquired by Upsher-Smith from Dr. Reddy's Laboratories Limited in a strategic effort to expand and diversify the Company's migraine portfolio.

Tosymra is supported by Upsher-Smith's Access Pathways® Program, which provides savings and support services for patients. The Platinum Pass® savings card enables commercially insured patients to pay as little as $0 per prescription.*

"We're excited to launch Tosymra, the third product in Upsher-Smith's growing migraine portfolio, which includes Qudexy® XR and Zembrace® SymTouch®," said Rusty Field, President and CEO, Upsher-Smith. "Many patients face challenges during migraine attacks that make available acute treatment options inadequate. Tosymra Nasal Spray offers an alternative for patients whose symptoms interfere with taking oral medication or who may be dissatisfied with their current treatment regimen."

Tosymra, which utilizes Intravail® technology, efficiently delivers sumatriptan intranasally and achieves median peak plasma concentration five minutes faster than injectable sumatriptan, 4 mg and 6 mg. Additionally, in the two hours following administration, a 10-mg dose of Tosymra demonstrated a markedly increased rate and extent of sumatriptan absorption when compared with Imitrex® 20-mg nasal spray**.

More than 36 million patients suffer from migraines and surveys have shown that a majority are willing to try other acute treatment options.[1] Patients currently using oral treatment options

may face challenges including nausea and gastroparesis or vomiting which may delay or limit oral medication absorption.

Important Patient Safety Information for Tosymra™ (sumatriptan) Nasal Spray

What important information should I know about TOSYMRA?

TOSYMRA can cause serious side effects, including: heart attack and other heart problems, which may lead to death. Stop using TOSYMRA and get emergency medical help right away if you have any of the following symptoms of a heart attack:

- discomfort in the center of your chest that lasts for more than a few minutes, or that goes away and comes back
- severe tightness, pain, pressure, or heaviness in your chest, throat, neck, or jaw
- pain or discomfort in your arms, back, neck, jaw, or stomach
- shortness of breath with or without chest discomfort
- breaking out in a cold sweat
- nausea or vomiting
- feeling lightheaded

TOSYMRA is not for people with risk factors for heart disease (high blood pressure, high cholesterol levels, smoking, overweight, diabetes, family history of heart disease) unless a heart exam is done and shows no problem.

Who should not use TOSYMRA?
Do not use TOSYMRA if you have:

- heart problems or a history of heart problems
- narrowing of blood vessels to your legs, arms, stomach, or kidney (peripheral vascular disease)
- uncontrolled high blood pressure
- severe liver problems
- hemiplegic migraines or basilar migraines. If you are not sure if you have these, ask your healthcare provider
- had a stroke, transient ischemic attacks (TIAs), or problems with your blood circulation
- taken any of the following medicines in the last 24 hours: almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, ergotamines, or dihydroergotamine. Ask your healthcare provider if you are not sure if your medicine is listed above
- are taking certain antidepressants, known as monoamine oxidase (MAO)-A inhibitors or it has been 2 weeks or less since you stopped taking a MAO-A inhibitor. Ask your healthcare provider or pharmacist for a list of these medicines if you are not sure.
- an allergy to sumatriptan or any of the ingredients in TOSYMRA.

What should I tell my healthcare provider before taking TOSYMRA?
Tell your healthcare provider about all of your medical conditions, and about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal

supplements.

What should I avoid while using TOSYMRA?
TOSYMRA can cause dizziness, weakness, or drowsiness. If you have these symptoms, do not drive a car, use machinery, or do anything where you need to be alert.

What are possible side effects of TOSYMRA?
TOSYMRA may cause serious side effects including:

- changes in color or sensation in your fingers and toes (Raynaud's syndrome)
- stomach and intestinal problems (gastrointestinal and colonic ischemic events). Symptoms of gastrointestinal and colonic ischemic events include: sudden or severe stomach pain, stomach pain after meals, weight loss, nausea or vomiting, constipation or diarrhea, bloody diarrhea, fever
- problems with blood circulation to your legs and feet (peripheral vascular ischemia). Symptoms of peripheral vascular ischemia include: cramping and pain in your legs or hips, feeling of heaviness or tightness in your leg muscles, burning or aching pain in your feet or toes while resting, numbness, tingling, or weakness in your legs, cold feeling or color changes in 1 or both legs or feet
- Increased blood pressure including a sudden severe increase (hypertensive crisis) even if you have no history of high blood pressure
- medication overuse headaches. Some people who use too much migraine medicine, such as TOSYMRA, for 10 or more days each month may have worse headaches (medication overuse headache). If your headaches get worse, your healthcare provider may decide to stop your treatment with TOSYMRA.
- serotonin syndrome. Serotonin syndrome is a rare but serious problem that can happen in people using TOSYMRA, especially if TOSYMRA is used with anti-depressant medicines called SSRIs or SNRIs.
    - **Call your healthcare provider right away if you have any of the following symptoms of serotonin syndrome:** mental changes such as seeing things that are not there (hallucinations), agitation, or coma; fast heartbeat; changes in blood pressure; high body temperature; tight muscles; or trouble walking
- hives (itchy bumps); swelling of your tongue, mouth, or throat
- seizures have happened in people taking sumatriptan who have never had seizures before

The most common side effects of TOSYMRA include: tingling, dizziness, feeling warm or hot, burning feeling, feeling of heaviness, feeling of pressure, flushing, feeling of tightness, numbness, application site (nasal) reactions, abnormal taste, and throat irritation.
Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of TOSYMRA. For more information, ask your healthcare provider or pharmacist.

This is the most important information to know about **TOSYMRA** but is not comprehensive. For more information, talk to your healthcare provider and read the **Patient Information and Instructions for Use** for **TOSYMRA**. You can also visit www.upsher-smith.com or call 1-888-650-3789.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

What is TOSYMRA used for?
TOSYMRA is a prescription medicine used to treat acute migraine headaches with or without aura in adults.

TOSYMRA is not used to treat other types of headaches such as hemiplegic (that make you unable to move on one side of your body) or basilar (rare form of migraine with aura) migraines. TOSYMRA is not used to treat cluster headaches.

TOSYMRA is not used to prevent or decrease the number of migraines you have. It is not known if TOSYMRA is safe and effective in children under 18 years of age.

Important Patient Safety Information for Zembrace® SymTouch®

What important information should I know about ZEMBRACE SymTouch?
ZEMBRACE SymTouch can cause serious side effects, including: heart attack and other heart problems, which may lead to death. Stop using ZEMBRACE SymTouch and get emergency medical help right away if you have any of the following symptoms of a heart attack:

- discomfort in the center of your chest that lasts for more than a few minutes, or that goes away and comes back
- severe tightness, pain, pressure, or heaviness in your chest, throat, neck, or jaw
- pain or discomfort in your arms, back, neck, jaw, or stomach shortness of breath
- breaking out in a cold sweat
- nausea or vomiting
- feeling lightheaded

ZEMBRACE SymTouch is not for people with risk factors for heart disease (high blood pressure, high cholesterol levels, smoking, overweight, diabetes, family history of heart disease) unless a heart exam is done and shows no problem.

Who should not use ZEMBRACE SymTouch?
Do not use ZEMBRACE SymTouch if you have:

- heart problems or a history of heart problems
- had a stroke, transient ischemic attacks (TIAs), or problems with your blood circulation
- narrowing of blood vessels to your legs or arms (peripheral vascular disease), stomach, or kidney
- uncontrolled high blood pressure
- hemiplegic migraines (that make you unable to move on one side of your body) or basilar (rare form of migraine with aura) migraines. If you are not sure if you have these, ask your healthcare provider
- taken any of the following medicines in the last 24 hours: almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, ergotamines, or dihydroergotamine. Ask your healthcare provider if you are not sure if your

medicine is listed above
- severe liver problems
- an allergy to sumatriptan or any of the components of ZEMBRACE SymTouch

What should I tell my healthcare provider before taking ZEMBRACE SymTouch?
Tell your healthcare provider about all of your medical conditions and about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

What should I avoid while using ZEMBRACE SymTouch?
ZEMBRACE SymTouch can cause dizziness, weakness, or drowsiness. If you have these symptoms, do not drive a car, use machinery, or do anything where you need to be alert.

What are possible side effects of ZEMBRACE SymTouch?
ZEMBRACE SymTouch may cause serious side effects including:

- changes in color or sensation in your fingers and toes (Raynaud's syndrome)
- stomach and intestinal problems (gastrointestinal and colonic ischemic events)
- problems with blood circulation to your legs and feet (peripheral vascular ischemia)
- hives (itchy bumps); swelling of your tongue, mouth, or throat
- medication overuse headaches. Some people who use too many ZEMBRACE SymTouch injections may have worse headaches (medication overuse headache)
- serotonin syndrome. Serotonin syndrome is a rare but serious problem that can happen in people using ZEMBRACE SymTouch, especially if used with antidepressant medicines
    - **Call your healthcare provider right away if you have any of the following** symptoms of serotonin syndrome: mental changes such as seeing things that are not there (hallucinations), agitation, or coma; fast heartbeat; changes in blood pressure; high body temperature; tight muscles; trouble walking; or nausea, vomiting, or diarrhea
- serious allergic reactions. Get medical help right away if you have any of these symptoms of a serious allergic reaction: swelling of your face, lips, mouth, or tongue; trouble breathing; wheezing; severe itching; skin rash, redness, or swelling; dizziness or fainting; fast heartbeat or pounding in your chest; or sweating
- Seizures have happened in people taking sumatriptan who have never had seizures before

The most common side effects of ZEMBRACE SymTouch include pain and redness at your injection site; tingling or numbness in your fingers or toes; dizziness; warm, hot, burning feeling to your face (flushing); discomfort or stiffness in your neck; feeling weak, drowsy, or tired.

This is the most important information to know about **ZEMBRACE SymTouch** but is not comprehensive. For more information, talk to your healthcare provider and read the **Patient Information** and **Instructions for Use** for **ZEMBRACE SymTouch**. You can also visit www.upsher-smith.com or call 1-888-650-3789.

You are encouraged to report negative side effects of prescription drugs to the FDA.

Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

INDICATION AND USAGE

What is ZEMBRACE SymTouch used for?

ZEMBRACE SymTouch is a prescription medicine used to treat acute migraine headaches with or without aura in adults who have been diagnosed with migraine.

ZEMBRACE SymTouch is not used to prevent or decrease the number of migraines you have. It is not known if ZEMBRACE SymTouch is safe and effective in children under 18 years of age.

Please see Patient Information, Instructions For Use and Full Prescribing Information for ZEMBRACE SymTouch or visit www.zembrace.com.

Important Patient Safety Information for Qudexy® XR (topiramate) Extended-Release Capsules

WHAT IS QUDEXY XR?

Qudexy® XR (topiramate) Extended-Release Capsules is a prescription medicine used:

- To prevent migraine headaches in adults and adolescents 12 years and older.
- To treat certain types of seizures (partial-onset seizures and primary generalized tonic-clonic seizures) in adults and children 2 years and older.
- With other medicines to treat certain types of seizures (partial-onset seizures, primary generalized tonic-clonic seizures, and seizures associated with Lennox-Gastaut syndrome) in adults and children 2 years and older.

WHAT IMPORTANT SAFETY INFORMATION SHOULD I KNOW?

Qudexy XR can cause serious side effects, including:

- **Serious eye problems,** which may include blurred or sudden decrease in vision, eye pain and redness or a blockage of fluid that may cause increased pressure in the eye (secondary angle closure glaucoma). If left untreated, this can lead to permanent vision loss.
- **Decreased sweating and fever.** People, especially children, should be watched for signs of decreased sweating and fever, especially in hot temperatures. Some people may need to be hospitalized for this condition.
- **Increased acid level in the blood (metabolic acidosis).** This may or may not cause symptoms. Symptoms may include feeling tired, decreased appetite, change in heartbeat, or trouble thinking clearly. If left untreated, metabolic acidosis can cause brittle or soft bones (osteoporosis, osteomalacia, osteopenia), kidney stones, can slow the rate of growth in children, and may possibly harm the unborn child of pregnant patients.
- **High blood ammonia levels.** High ammonia in the blood can affect mental activities, slow alertness and cause tiredness or vomiting. This can also happen when Qudexy XR is taken with a medicine called valproic acid (e.g., Depakene® and Depakote®).
- **Kidney stones.** Drink plenty of fluids when taking Qudexy XR to decrease your chances of getting kidney stones.
- **Low body temperature.** Taking Qudexy XR when you are also taking valproic acid may cause a drop in body temperature to less than 95°F, tiredness, confusion, or coma.

- **Effects on thinking and alertness.** Qudexy XR may affect how you think, and can cause confusion, problems with concentration, attention, memory, or speech. Qudexy XR may cause depression or mood problems, tiredness, and sleepiness.
- **Dizziness or loss of muscle coordination.**

Call your healthcare provider right away if you have any of the above symptoms.

Like other antiepileptic drugs, Qudexy XR may cause suicidal thoughts or actions in a very small number of people, about 1 in 500. Before taking Qudexy XR, tell your healthcare provider if you have or have had depression, mood problems, or suicidal thoughts or behavior. Call a healthcare provider right away if you have: thoughts about suicide or dying; attempt to commit suicide; have new or worsening depression or anxiety; feel agitated or restless; experience panic attacks, have trouble sleeping (insomnia); have new or worsening irritability; feel or act aggressive, angry, or violent; act on dangerous impulses; experience an extreme increase in activity and talking (mania); or other unusual changes in your behavior or mood.

Qudexy XR can harm your unborn baby. All women of childbearing age should talk to their healthcare provider about possible alternative treatments. If you take Qudexy XR during pregnancy, your baby has a higher risk for birth defects called cleft lip and cleft palate. These defects can begin early in pregnancy, even before you know you are pregnant. Also, if you take Qudexy XR during pregnancy, your baby may be smaller than expected at birth; the long-term effects of this are not known. If the decision is made to use Qudexy XR, you should use effective birth control (contraception).**Tell your healthcare provider right away if you become, or plan to become pregnant while taking Qudexy XR.**

The most common side effects of Qudexy XR include: tingling of the arms and legs (paresthesia), not feeling hungry, weight loss, nervousness, nausea, speech problems, tiredness, dizziness, sleepiness/drowsiness, a change in the way foods taste, upper respiratory tract infection, decreased feeling or sensitivity especially in the skin, slow reactions, difficulty with memory, fever, abnormal vision, diarrhea, and pain in the abdomen. These are not all the possible side effects of Qudexy XR. For more information, ask your healthcare provider or pharmacist.

Before taking Qudexy XR, tell your healthcare provider about all of your medical conditions, including if you: have had depression, mood problems, or suicidal thoughts or behavior; have kidney problems, kidney stones, or are getting kidney dialysis; have a history of metabolic acidosis (too much acid in the blood); have liver problems; have weak, brittle or soft bones (osteomalacia, osteoporosis, osteopenia, or decreased bone density); have lung or breathing problems; have eye problems, especially glaucoma; have diarrhea; have a growth problem; are on a diet high in fat and low in carbohydrates, which is called a ketogenic diet; are having surgery; are pregnant or planning to become pregnant; or if you are breastfeeding. The medicine in Qudexy XR (topiramate) passes into your breast milk. It is not known if the medicine, topiramate, that passes into breast milk can harm your baby. Talk with your healthcare provider about the best way to feed your baby if you take Qudexy XR.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Especially tell your healthcare provider if you take metformin (e.g., Glucophage); valproic acid (e.g., Depakene or Depakote); any medicines that impair or decrease your thinking, concentration, or muscle coordination; birth control pills (Qudexy XR may make birth control pills less effective); medicines used to prevent seizures; or any other carbonic anhydrase inhibitors (e.g., zonisamide or acetazolamide).

Do not stop Qudexy XR without first talking to a healthcare provider. If you have epilepsy and you stop taking Qudexy XR suddenly, you may have seizures that do not stop. Your healthcare provider will tell you how to stop taking Qudexy XR slowly.

Do not drink alcohol while taking Qudexy XR. Qudexy XR and alcohol can cause side effects such as sleepiness and dizziness.

Do not drive a car, swim, climb, or operate heavy machinery until you know how Qudexy XR affects you. Qudexy XR can slow your thinking and motor skills, and may affect vision. Even when taking Qudexy XR, some patients with epilepsy will continue to have unpredictable seizures.

This is the most important information to know about Qudexy XR but is not comprehensive. For more information, talk to your healthcare provider and read the Medication Guide for Qudexy XR. You can also visit www.upsher-smith.com or call 1-888-650-3789.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

About Intravail®

Intravail® is a registered trademark of Neurelis, Inc. Intravail® permeation enhancement technology enables the non-invasive delivery of a broad range of protein, peptide and non-peptide drugs (up to 30,000 daltons in size) that can currently only be administered by injection. Intravail® can be utilized via the oral, buccal, dermal, and intranasal routes of drug administration.

About Upsher-Smith

Upsher-Smith Laboratories, LLC is a trusted U.S. pharmaceutical company that strives to improve the health and lives of patients through an unwavering commitment to high-quality products and sustainable growth. Since 1919, it has brought generics and brands to a wide array of customers backed by an attentive level of service, strong industry relationships, and dedication to uninterrupted supply.

As Upsher-Smith celebrates its 100-year anniversary, the company enters a new ambitious era that has been accelerated by its 2017 acquisition by Sawai Pharmaceutical Co., Ltd. Upsher-Smith and Sawai plan to leverage each other for growth worldwide and embark on an exciting new chapter as they seek to deliver the best value for their stakeholders, and most importantly, Do More Good™ for the patients they serve. For more information, visit www.upsher-smith.com.

Intravail is a registered trademark of Neurelis, Inc.

Imitrex is a registered trademark of Glaxo Group Limited.

*Restrictions apply. Maximum of eight single-dose nasal spray units per month. Medicare, Medicaid, and other federal and state health care program patients are not eligible.

**Data derived from a pharmacokinetic pilot study of 18 healthy subjects.

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Reference

1. Bigal M, Rapoport A, Aurora S, Sheftell F, Tepper S, Dahlof C., Satisfaction with Current Migraine Therapy: Experience From 2 Centers in US and Sweden. Headache. 2007 Apr;47(4):475-9. https://doi.org/10.1111/j.1526-4610.2007.00752.x

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