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Dr. Reddy's Laboratories and its U.S. subsidiary, Promius Pharma, announce FDA approval for TOSYMRA™ (sumatriptan nasal spray) 10 mg, in the U.S. market

Hyderabad, India, January 28, 2019

For Immediate Release

Hyderabad, India and Princeton, NJ, USA, January 28, 2019 — Dr. Reddy's Laboratories Ltd. (BSE: 500124, NSE: DRREDDY, NYSE: RDY) and its subsidiary, Promius Pharma, LLC today announced the approval of TOSYMRA (previously known as DFN-02) by the U.S. Food and Drug Administration (FDA). TOSYMRA is indicated for the acute treatment of migraine with or without aura in adults. TOSYMRA is the latest product to join the Promius Pharma acute migraine treatment portfolio. The company is working toward commercialization of this product.

"We are excited about the approval of TOSYMRA. This approval affirms our ability to develop well-differentiated products to meet the unmet needs of patients with migraine and HCPs treating them," said G.V. Prasad, Co-Chairman and CEO, Dr. Reddy's Laboratories.

According to Dr. Anil Namboodiripad, PhD, President, Promius Pharma, "TOSYMRA nasal spray is formulated using a proprietary novel excipient known as Intravail® to achieve blood levels similar to a 4-mg sumatriptan subcutaneous injection, resulting in rapid onset of action. Independent research shows that 26% to 40% of migraine patients are not optimally controlled with their current treatment.¹ For patients who suffer from the debilitating and disruptive effects of migraine, there continues to be a need for reliable and efficacious treatment options. At Promius, we are committed to developing new ways of improving patient experiences. TOSYMRA is a mist-like nasal spray that acts rapidly and is well tolerated."

Important Patient Safety Information:

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.

You are encouraged to report negative side effects of prescription drugs. To report SUSPECTED SIDE EFFECTS, call Promius Pharma at 1-888-966-8766 or contact the FDA at 1-800-FDA-1088 (1-800-332-1088) or online at <http://www.fda.gov/Safety/MedWatch>

Please see [Patient Information](#), [Instructions for Use](#) and [Full Prescribing Information](#) for TOSYMRA

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.

About Intravail®

Intravail® is a registered trademark of Neurelis, Inc. Intravail® drug delivery 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.

Reference: 1. Pavlovic JM, Buse DC, Reed ML, et al. Triptan use and discontinuation among a population sample of persons with migraine: Results from Migraine in America Symptoms and Treatment (MAST) Study. Presented at: 60th Annual Scientific Meeting of the American Headache Society®; June 28, 2018; San Francisco, CA.

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About Dr. Reddy's: Dr. Reddy's Laboratories Ltd. (BSE: 500124, NSE: DRREDDY, NYSE: RDY) is an integrated pharmaceutical company, committed to providing affordable and innovative medicines for healthier lives. Through its three businesses—Pharmaceutical Services & Active Ingredients, Global Generics, and Proprietary Products—Dr. Reddy's offers a portfolio of products and services including APIs, custom pharmaceutical services, generics, biosimilars, and differentiated formulations. Our major therapeutic areas of focus are gastroenterology, cardiology, diabetology, oncology, pain management and dermatology. Dr. Reddy's operates in markets across the globe. Our major markets include USA, India, Russia & CIS countries, and Europe. For more information, log on to: www.drreddys.com.

About Promius Pharma LLC

Promius Pharma is a wholly-owned subsidiary of Dr. Reddy's Laboratories, one of the largest and most respected pharmaceutical companies in the world. With a robust commercial infrastructure and extensive research and development capabilities through its parent company, Promius Pharma is committed to bringing new products to market that meet patients' needs in dermatology and neurology. For more information, visit www.promiuspharma.com.

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The company assumes no obligation to update any information contained herein.