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# Promius Pharma Announces ZEMBRACE® SymTouch® (Sumatriptan Injection) 3 mg Achieves Primary Endpoint in Post-Approval Clinical Trial

Princeton, NJ, USA. November 15, 2017 – Promius Pharma LLC announced today that ZEMBRACE® SymTouch® (sumatriptan injection) 3 mg, an acute migraine headache treatment on the market since April 2016, achieved its primary and multiple secondary endpoints in a 268-subject, post-approval clinical trial. Since launch, more than 2,000 neurologists and headache specialists in the country have prescribed ZEMBRACE SymTouch to thousands of patients.

Overall, the trial found that a significantly higher proportion of subjects experienced migraine pain freedom at 2 hours postdose with ZEMBRACE SymTouch compared with placebo: 51.0% (n=104) versus 30.8% (n=104), *P*<.01. Additional endpoints were also met, including pain freedom at 1 hour postdose (34.6% versus 19.8%, *P*<.05) and alleviating the patients' most bothersome symptom (64.1% versus 48.1%, *P*<.05).

ZEMBRACE SymTouch was well tolerated with 33.3% of subjects experiencing treatment-emergent adverse events (TEAEs) compared with 13.4% of subjects using placebo (23% overall). A total of 7.2% of subjects experienced triptan-related TEAEs within 2 hours postdose (1.7% for placebo; 4.3% overall). Injection site reaction incidence was 21.6% for ZEMBRACE SymTouch versus 11.8% for placebo (16.5% overall). There were no treatment-emergent serious adverse events.

"This multicenter, randomized, double-blind, placebo-controlled trial demonstrates that the 3 mg dose of sumatriptan in ZEMBRACE SymTouch provided rapid, complete pain relief in a significant proportion of patients with a low rate of side effects and no serious adverse events," said study author Stephen Landy MD, Director Baptist Medical Group Headache Clinic, Memphis, TN. "Physicians can consider this low-dose 3 mg injectable sumatriptan as an effective treatment option for their migraine patients."

## IMPORTANT SAFETY INFORMATION

ZEMBRACE SymTouch is contraindicated in patients with:

- Ischemic Coronary Artery Disease (CAD) or coronary artery vasospasm (including Prinzmetal's angina), Wolff-Parkinson-White syndrome or arrhythmias associated with other cardiac accessory conduction pathway disorders
- Uncontrolled hypertension, history of stroke or transient ischemic attack (TIA) or history of hemiplegic or basilar migraine
- Peripheral vascular disease

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- Ischemic bowel disease
- Recent (i.e., within 24 hours) use of ergotamine-containing medication, ergot derivatives, or another 5-$HT_1$ agonist
- Concurrent or recent (within 2 weeks) use of an MAO-A inhibitor
- Known hypersensitivity to sumatriptan
- Severe hepatic impairment

There have been rare reports of serious cardiac adverse reactions, including acute myocardial infarction, occurring within a few hours following administration of sumatriptan injection. Some of these reactions occurred in patients without known CAD. 5-$HT_1$ agonists, including ZEMBRACE SymTouch, may cause coronary artery vasospasm. Life-threatening disturbances of cardiac rhythm leading to death in some cases, have been reported within a few hours following the administration of 5-$HT_1$ agonists. Cerebrovascular events including cerebral hemorrhage, subarachnoid hemorrhage, and stroke have occurred in patients treated with 5-$HT_1$ agonists, and some have resulted in fatalities. Discontinue ZEMBRACE SymTouch if any of these events occur.

Perform a cardiovascular evaluation in triptan-naive patients who have multiple cardiovascular risk factors prior to receiving ZEMBRACE SymTouch. For patients with multiple cardiovascular risk factors who have a negative cardiovascular evaluation, consider administering the first dose of ZEMBRACE SymTouch in a medically supervised setting and consider periodic follow up. Sensations of tightness, pain, pressure, and heaviness in the precordium, throat, neck, and jaw commonly occur after treatment with sumatriptan injection and are usually non-cardiac in origin.

ZEMBRACE SymTouch may cause non-coronary vasospastic reactions, such as peripheral vascular ischemia, gastrointestinal vascular ischemia and infarction, splenic infarction, and Raynaud's syndrome. Overuse of acute migraine drugs may lead to exacerbation of headache (medication overuse headache). Detoxification of patients, including withdrawal of the overused drugs, and treatment of withdrawal symptoms may be necessary.

Serotonin syndrome may occur with ZEMBRACE SymTouch, particularly during co-administration with selective serotonin reuptake inhibitors (SSRIs), serotonin norepinephrine reuptake inhibitors (SNRIs), tricyclic antidepressants (TCAs), and MAO inhibitors. Significant elevation in blood pressure, including hypertensive crisis with acute impairment of organ systems, has been reported on rare occasions in patients treated with 5-$HT_1$ agonists, including patients without a history of hypertension. Monitor blood pressure in patients treated with ZEMBRACE SymTouch. Discontinue ZEMBRACE SymTouch if serotonin syndrome is suspected or hypertensive crisis is observed.

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Seizures have been reported following administration of sumatriptan. Some have occurred in patients with either a history of seizures or concurrent conditions predisposing to seizures. ZEMBRACE SymTouch should be used with caution in patients with a history of epilepsy or conditions associated with a lowered seizure threshold.

Most common adverse reactions (≥5% and > placebo) were injection site reactions, tingling, dizziness/vertigo, warm/hot sensation, burning sensation, feeling of heaviness, pressure sensation, flushing, feeling of tightness, and numbness.

These are not all the side effects associated with ZEMBRACE SymTouch. Advise the patient to read the FDA-approved patient labeling. Please see Patient Information, Instructions For Use and Full Prescribing Information for ZEMBRACE SymTouch at www.ZEMBRACE.com.

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.

**INDICATION AND USAGE**

ZEMBRACE SymTouch is indicated for the acute treatment of migraine with or without aura in adults.

Limitations of Use:

- Use only if a clear diagnosis of migraine has been established. If a patient has no response to the first migraine attack treated with ZEMBRACE SymTouch, reconsider the diagnosis before ZEMBRACE SymTouch is administered to treat any subsequent attacks.
- ZEMBRACE SymTouch is not indicated for the prevention of migraine attacks.

**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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