Endo Announces Agreement with Slayback Pharma to Distribute Prevduo™ (neostigmine methylsulfate and glycopyrrolate injection), the First and Only FDA-Approved Neostigmine-Glycopyrrolate Combination Product in the U.S.

April 26, 2023

DUBLIN, April 26, 2023 /PRNewswire/ -- Endo International plc (OTC: ENDPQ) announced today that its subsidiaries Endo Ventures Limited and Par Pharmaceutical, Inc. (collectively "Endo") have executed an agreement with Slayback Pharma LLC to distribute Slayback's Prevduo ™ (neostigmine methylsulfate and glycopyrrolate injection) pre-filled syringe on an exclusive basis in the U.S. The U.S. Food and Drug Administration (FDA) approved Prevduo ™ in February 2023 for the reversal of the effects of nondepolarizing neuromuscular blocking agents (NMBA) after surgery, while decreasing the peripheral muscarinic effects (e.g., bradycardia and excessive secretions) associated with cholinesterase inhibition following NMBA reversal administration.

Endo will commercialize Prevduo ™ through its Par Sterile Products business and expects to launch the product in June 2023.

When launched, Prevduo ™ will be the first and only FDA-approved neostigmine–glycopyrrolate combination product in the U.S. Both neostigmine methylsulfate and glycopyrrolate have been approved in the U.S. as single, active ingredient drug products. Neostigmine is always administered in conjunction with glycopyrrolate, and currently, its administration requires two syringes.

"Prevduo ™ further strengthens our commitment to supporting healthcare providers and their patients through ready-to-use products that streamline operations," said Scott Sims, Senior Vice President and General Manager, Injectable Solutions & Generics at Endo. "We're proud to partner with Slayback to bring this critical care product to market and help hospitals deliver quality patient care."

"Following the development and FDA approval of Prevduo ™, we're pleased to partner with Endo and tap into Endo's proven capabilities in commercializing injectable solutions, including ready-to-use products," said Ajay Singh, Founder and CEO of Slayback Pharma.

Ready-to-use, or RTU, products streamline operations for hospitals by eliminating the need to prepare or transfer the product before patient administration. This may reduce waste and costs, optimize convenience and workflow and reduce the chance for preparation error—all of which support quality patient care.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

PREVDUO ™ is contraindicated in patients with:

- Known hypersensitivity to neostigmine methylsulfate (known hypersensitivity reactions have included urticaria, angioedema, erythema multiforme, generalized rash, facial swelling, peripheral edema, pyrexia, flushing, hypotension, bronchospasm, bradycardia and anaphylaxis) and glycopyrrolate or any inactive ingredients.
- Peritonitis or mechanical obstruction of the intestinal or urinary tract.
- Glaucoma; obstructive uropathy (for example, bladder neck obstruction due to prostatic hypertrophy); obstructive disease of the gastrointestinal tract (as in achalasia, pyloroduodenal stenosis, etc.); paralytic ileus, intestinal atony of the elderly or debilitated patient; unstable cardiovascular status in acute hemorrhage; severe ulcerative colitis; toxic megacolon complicating ulcerative colitis; myasthenia gravis.

WARNINGS AND PRECAUTIONS

Bradycardia: Neostigmine, a component of PREVDUO ™, is associated with bradycardia. Consideration should be given to administration of

glycopyrrolate prior to neostigmine (i.e., as separate products) in patients with bradycardia or in patients in whom bradycardia, a known risk of neostigmine methysulfate, may cause hemodynamic instability.

Serious Adverse Reactions in Patients with Certain Coexisting Conditions: PREVDUO ™ should be used with caution in patients with coronary artery disease, congestive heart failure, cardiac arrhythmias, recent acute coronary syndrome, hypertension, myasthenia gravis and hyperthyroidism. Because of the known pharmacology of neostigmine methylsulfate as an acetylcholinesterase inhibitor, cardiovascular effects such as bradycardia, hypotension or dysrhythmia would be anticipated. In patients with acute cardiovascular conditions such as coronary artery disease, cardiac arrhythmias or recent acute coronary syndrome, the risk of blood pressure and heart rate complications may be increased. Risk of these complications may also be increased in patients with myasthenia gravis.

Hypersensitivity: Because of the possibility of hypersensitivity, medications to treat anaphylaxis should be readily available.

Neuromuscular Dysfunction: Large doses of PREVDUO ™ administered when neuromuscular blockade is minimal can produce neuromuscular dysfunction. The dose of PREVDUO™ should be reduced if recovery from neuromuscular blockade is nearly complete.

Cholinergic Crisis: It is important to differentiate between myasthenic crisis and cholinergic crisis caused by overdosage of neostigmine. Both conditions result in extreme muscle weakness but require radically different treatment.

Precipitation of Acute Glaucoma: Glycopyrrolate, a component of PREVDUO ™, is contraindicated in patients with glaucoma because it may cause mydriasis and increase intraocular pressure. Advise patients with glaucoma to promptly seek medical care in the event that they experience symptoms of acute angle closure glaucoma (pain and reddening of the eyes, accompanied by dilated pupils).

Drowsiness and Blurred Vision: Glycopyrrolate, a component of PREVDUO ™, may cause drowsiness or blurred vision. Warn patients not to participate in activities requiring mental alertness, such as operate a motor vehicle or other machinery or perform hazardous work until these issues resolve.

Heat Prostration: Glycopyrrolate, a component of PREVDUO ™, may cause heat prostration (due to decreased sweating) in presence of fever, high environmental temperature, and/or during physical exercise, particularly in children and the elderly. Advise patients to avoid exertion and high environmental temperature after receiving PREVDUO ™.

Intestinal Obstruction: Diarrhea may be an early symptom of incomplete intestinal obstruction, especially in patients with ileostomy or colostomy. In this instance treatment with Glycopyrrolate, a component of PREVDUO ™, is inappropriate and possibly harmful. Avoid use in patients with these conditions.

Tachycardia: Investigate any tachycardia before giving Glycopyrrolate, a component of PREVDUO ™ because an increase in the heart rate may occur. Use with caution in patients with coronary artery disease, congestive heart failure, cardiac arrhythmias, hypertension, or hyperthyroidism.

ADVERSE REACTIONS

- Most common adverse reactions to neostigmine during treatment: bradycardia, nausea, vomiting, blurred vision and photophobia.
- Most common adverse reactions to glycopyrrolate are related to anticholinergic pharmacology and may include xerostomia (dry mouth); urinary hesitancy and retention; blurred vision and photophobia due to mydriasis (dilation of the pupil); cycloplegia; increased ocular tension; tachycardia; bradycardia; palpitation; and decreased sweating.

DRUG INTERACTIONS

Neostigmine Methylsulfate: The pharmacokinetic interaction between neostigmine methylsulfate and other drugs has not been studied. Neostigmine methylsulfate is metabolized by microsomal enzymes in the liver. Use with caution when using neostigmine methylsulfate with other drugs which may alter the activity of metabolizing enzymes or transporters.

Glycopyrrolate: The concurrent use of glycopyrrolate with other anticholinergics or medications with anticholinergic activity, such as phenothiazines, antiparkinson drugs, or tricyclic antidepressants, may intensify the antimuscarinic effects and may result in an increase in anticholinergic side effects.

INDICATION AND USAGE

PREVDUO ™, a fixed dose combination of cholinesterase inhibitor and antimuscarinic agent, is indicated in patients age two years and above for the reversal of the effects of nondepolarizing neuromuscular blocking agents (NMBA) after surgery, while decreasing the peripheral muscarinic effects (e.g., bradycardia and excessive secretions) associated with cholinesterase inhibition following NMBA reversal administration.

Please click for full Prescribing Information.

About Endo

Endo (OTC: ENDPQ) is a specialty pharmaceutical company committed to helping everyone we serve live their best life through the delivery of quality, life-enhancing therapies. Our decades of proven success come from passionate team members around the globe collaborating to bring treatments forward. Together, we boldly transform insights into treatments benefiting those who need them, when they need them. Learn more at www.endo.com or connect with us on LinkedIn.

About Slayback Pharma LLC

Slayback is a New-Jersey based pharmaceutical company focused on the development and commercialization of complex generic and specialty pharmaceutical products.

Cautionary Note Regarding Forward-Looking Statements

Certain information in this press release may be considered "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 and any applicable Canadian securities legislation including, but not limited to, the statements by Messrs. Sims and Singh, any statements relating to product launch, commercialization, sales, supply or distribution, and any statements that refer to expected, estimated or anticipated future results or that do not relate solely to historical facts. Statements including words or phrases such as "believe," "expect," "anticipate," "intend," "estimate," "plan," "will," "may," "look forward," "intend," "guidance," "future," "potential" or similar expressions are forward-looking statements. All forward-looking statements in this communication reflect the Company's current views as of the date of this communication about its plans, intentions, expectations, strategies and prospects, which are based on the information currently available to it and on assumptions it has made. Actual results may differ materially and adversely from current expectations based on a number of factors, including, among other things, the outcome of the Company's contingency planning and restructuring activities; the timing, impact or results of any pending or future litigation, investigations, proceedings or claims, including opioid, tax and antitrust related matters; any actual or contingent liabilities; settlement discussions or negotiations; the

Company's liquidity, financial performance, cash position and operations; the risks and uncertainties associated with chapter 11 proceedings; the time, terms and ability to confirm a sale of the Company's businesses under Section 363 of the U.S. Bankruptcy Code; the risk that the Company's chapter 11 cases may be converted to cases under chapter 7 of the Bankruptcy Code; the adequacy of the capital resources of the Company's businesses and the difficulty in forecasting the liquidity requirements of the operations of the Company's businesses; the unpredictability of the Company's financial results; the Company's ability to discharge claims in chapter 11 proceedings; negotiations with the holders of the Company's indebtedness and its trade creditors and other significant creditors; the risks and uncertainties with performing under the terms of the restructuring support agreement and any other arrangement with lenders or creditors while in chapter 11 proceedings; the performance, including the approval, introduction, and consumer and physician acceptance of new products and the continuing acceptance of currently marketed products; and the Company's ability to obtain and successfully manufacture, maintain and distribute a sufficient supply of products to meet market demand in a timely manner. The Company expressly disclaims any intent or obligation to update these forward-looking statements, except as required to do so by law.

Additional information concerning risk factors, including those referenced above, can be found in press releases issued by the Company, as well as the Company's public periodic filings with the U.S. Securities and Exchange Commission and with securities regulators in Canada, including the discussion under the heading "Risk Factors" in the Company's most recent Annual Report on Form 10-K and any subsequent Quarterly Reports on Form 10-Q or other filings with the U.S. Securities and Exchange Commission.

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