Endo Announces Licensing Agreement for Paladin Labs Inc. to Commercialize Abaloparatide in Canada

January 5, 2021

DUBLIN, Jan. 5, 2021 /PRNewswire/ -- Endo International plc (NASDAQ: ENDP) announced today that its subsidiary Endo Ventures Limited has entered into definitive agreements with Radius Health, Inc. (NASDAQ: RDUS) to register, commercialize and distribute abaloparatide on an exclusive basis in Canada. Paladin Labs Inc., an operating company of Endo, will be responsible for all commercial activities related to abaloparatide. Under the agreement, Endo obtained the rights to abaloparatide-subcutaneous injection (abaloparatide-SC) and abaloparatide-transdermal patch (abaloparatide-TD), a novel formulation and route of administration currently undergoing clinical development.

Abaloparatide is a parathyroid hormone-related protein (PTHrP) analog under investigation for osteoporosis; it is not approved in Canada. Abaloparatide is an anabolic (bone-forming) agent self-administered once daily. Paladin plans to file a New Drug Submission (NDS) with Health Canada for abaloparatide-SC by the first quarter of 2022.

In accordance with the terms of the agreements, if abaloparatide is approved in Canada, Paladin will be responsible for the registration, distribution, sales, marketing, medical affairs, pricing and reimbursement activities in connection with commercialization while Radius will be responsible for supplying the drug to Paladin.

"We are very pleased to work with Radius to possibly bring a new treatment option to the market for Canadian osteoporosis patients," said Livio Di Francesco, Vice President and General Manager of Paladin. "This transaction marks our entry into the endocrine and metabolic therapeutic space. Abaloparatide has shown promising clinical evidence to address an unmet need and it has the potential to become a very important addition to our existing Canadian portfolio."

About Abaloparatide:

Abaloparatide is a PTH-1 selective parathyroid hormone-related protein (PTHrP) analog used to treat osteoporosis. In May 2017, the U.S. Food and Drug Administration approved abaloparatide-SC, marketed under the trade name TYMLOS®, for the treatment of postmenopausal women with osteoporosis at high risk for fracture, defined as history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy. This product is not approved in Canada. In 2019, Radius initiated the wearABLe study, a Phase III clinical trial comparing the safety and efficacy of abaloparatide-TD to abaloparatide-SC. The wearABLe study reached full enrollment in September 2020 and top line results are expected in the fourth quarter of 2021.

About Osteoporosis:

Osteoporosis is a progressive metabolic bone disorder characterized by compromised bone mineral density (BMD) and bone quality, predisposing to an increased risk of fracture. The World Health Organization defines the diagnostic threshold for osteoporosis as BMD measurement 2.5 standard deviations or more below the mean of a young, healthy reference group. Osteoporosis affects primarily women over the age of 50; the rapid decrease in estrogen that follows menopause is one major cause. In more severe cases, osteoporosis can cause recurring fractures of the spine, upper limbs and hip, which are in turn associated with significant morbidity and mortality.

About Endo and Paladin Labs Inc.

Endo (NASDAQ: ENDP) 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 a global team of passionate employees collaborating to bring the best 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.

Paladin Labs Inc., headquartered in Montreal, Canada, is a specialty pharmaceutical company focused on acquiring or in-licensing innovative pharmaceutical products for the Canadian market. Paladin has a focused marketing and sales organization that has helped it evolve into one

of Canada's leading specialty pharmaceutical companies. Paladin is an operating company of Endo International plc. For more information visit: www.endo.com or www.paladin-labs.com.

About Radius Health, Inc.

Radius is a science-driven fully integrated biopharmaceutical company that is committed to developing and commercializing innovative endocrine therapeutics. For more information, please visit www.radiuspharm.com.

U.S. Important Safety Information about TYMLOS® (abaloparatide) Injection

WARNING: RISK OF OSTEOSARCOMA

- Abaloparatide caused a dose-dependent increase in the incidence of osteosarcoma (a malignant bone tumor) in male and female rats. The effect was observed at systemic exposures to abaloparatide ranging from 4 to 28 times the exposure in humans receiving the 80-mcg dose. It is unknown if TYMLOS will cause osteosarcoma in humans.
- The use of TYMLOS is not recommended in patients at increased risk of osteosarcoma including those with Paget's disease of bone or unexplained elevations of alkaline phosphatase, open epiphyses, bone metastases or skeletal malignancies, hereditary disorders predisposing to osteosarcoma, or prior external beam or implant radiation therapy involving the skeleton.
- Cumulative use of TYMLOS and parathyroid hormone analogs (e.g., teriparatide) for more than 2 years during a patient's lifetime is not recommended.

Orthostatic Hypotension: Orthostatic hypotension may occur with TYMLOS, typically within 4 hours of injection. Associated symptoms may include dizziness, palpitations, tachycardia or nausea, and may resolve by having the patient lie down. For the first several doses, TYMLOS should be administered where the patient can sit or lie down if necessary.

Hypercalcemia: TYMLOS may cause hypercalcemia. TYMLOS is not recommended in patients with pre-existing hypercalcemia or in patients who have an underlying hypercalcemic disorder, such as primary hyperparathyroidism, because of the possibility of exacerbating hypercalcemia.

Hypercalciuria and Urolithiasis: TYMLOS may cause hypercalciuria. It is unknown whether TYMLOS may exacerbate urolithiasis in patients with active or a history of urolithiasis. If active urolithiasis or pre-existing hypercalciuria is suspected, measurement of urinary calcium excretion should be considered.

Adverse Reactions: The most common adverse reactions (incidence ≥2%) are hypercalciuria, dizziness, nausea, headache, palpitations, fatigue, upper abdominal pain and vertigo.

INDICATIONS AND USAGE

TYMLOS is indicated for the treatment of postmenopausal women with osteoporosis at high risk for fracture defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy. In postmenopausal women with osteoporosis, TYMLOS reduces the risk of vertebral fractures and nonvertebral fractures.

Limitations of Use

Because of the unknown relevance of the rodent osteosarcoma findings to humans, cumulative use of TYMLOS and parathyroid hormone analogs (e.g., teriparatide) for more than 2 years during a patient's lifetime is not recommended.

For the TYMLOS prescribing information, including Boxed Warning, please visit www.tymlospi.com.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements, including the statements by Mr. Di Francesco and other statements relating to the regulatory approval, distribution, sales, marketing, medical affairs, pricing, reimbursement activities, commercialization, safety, efficacy, clinical benefit, clinical trials, market potential and product potential of abaloparatide-SC and abaloparatide-TD, within the meaning of the Private Securities Litigation Reform Act of 1995 and the relevant Canadian securities legislation. Statements including words such as "believes," "expects," "anticipates," "intends," "estimates," "plan," "will," "may," "look forward," "intend," "guidance," "future" or similar expressions are forward-looking statements. Because these statements reflect current views, expectations and beliefs concerning future events, these forward-looking statements involve risks and uncertainties and readers should not place undue reliance on them, or any other forward-looking statements or information in this news release. Investors should note that many factors, as more fully described in the documents led by Endo International plc with securities regulators in the United States and Canada including under the caption "Risk Factors" in Endo's Form 10-K, Form 10-Q and Form 8-K filings with the Securities and Exchange Commission and with securities regulators in Canada on System for Electronic Document Analysis and Retrieval ("SEDAR") and as otherwise enumerated herein or therein, could affect Endo's future financial results and could cause Endo's actual results to differ materially from those expressed in any forward-looking statements. The forward-looking statements in this press release are qualified by these risk factors which, individually or in the aggregate, could cause Endo's actual results to differ materially from expected and historical results. Endo assumes no obligation to publicly update any forward-looking statements, whether as a result of new information, future developments or otherwise, except as may be required under applicable securities law.

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