Radius Health Announces Commercial Agreement with Paladin Labs for Abaloparatide in Canada

January 5, 2021

- Agreement incorporates TYMLOS® and abaloparatide-TD
- Consideration includes upfront payment, milestones based on clinical, regulatory and commercial progression, as well as royalties
- Key first step in expanding the global footprint for the abaloparatide asset beyond the U.S. and Japan; a key focus area for the company for 2021

BOSTON, Jan. 05, 2021 (GLOBE NEWSWIRE) -- Radius Health, Inc. (“Radius” or the “Company”) (Nasdaq: RDUS) today announced that the Company has entered into definitive agreements with Endo Ventures Limited, a subsidiary of Endo International plc (“Endo”) (NASDAQ: ENDP), to register, commercialize, and distribute abaloparatide on an exclusive basis in Canada. Paladin Labs Inc. (“Paladin”), an operating company of Endo, will be responsible for all commercial activities related to abaloparatide. Under the terms of the agreements, Paladin will pay Radius upfront and milestone payments up to approximately $8.0 million and tiered royalties up to the mid-twenties on net sales in Canada.

In accordance with the terms of the agreements, Paladin will license Radius’ abaloparatide subcutaneous injection, TYMLOS ®, and abaloparatide novel transdermal device (“abaloparatide-TD”) for the Canadian market. Paladin will be responsible for the registration distribution, sales, marketing, medical affairs, pricing and reimbursement activities in connection with abaloparatide. Radius will be responsible for supplying the drug to Paladin.

“Reaching an agreement with Paladin in Canada demonstrates both the interest in and opportunity to expand the global footprint of abaloparatide in select ex-U.S. markets. This is one of several key priorities for us and our goal is to make additional progress throughout 2021,” said Cole Ikkala, Head of Business Development at Radius.

Paladin is targeting to file a New Drug Submission (NDS) to Health Canada for TYMLOS® by the first quarter of 2022. The Company will provide additional business updates as and when appropriate.

About TYMLOS® (abaloparatide) Injection

TYMLOS® (abaloparatide) injection was approved by the U.S. Food and Drug Administration 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.

IMPORTANT SAFETY INFORMATION

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.

About Abaloparatide-TD and wearABLe Phase 3 Study
Abaloparatide-TD was developed in a collaboration between Radius and Kindeva Drug Delivery ("Kindeva") (formerly 3M Drug Delivery Systems) with the application of Kindeva's innovative microstructured transdermal patch technology. The Phase 3 wearABLe abaloparatide-TD study is the first pivotal study to evaluate treatment using a novel non-injectable delivery of an anabolic therapy. The wearABLe Phase 3 study is a pivotal, randomized, open label, active-controlled, bone mineral density ("BMD") non-inferiority bridging study that will evaluate the efficacy and safety of abaloparatide-TD versus TYMLOS® (abaloparatide) injection in approximately 500 patients with postmenopausal osteoporosis at high risk for fracture. The primary endpoint of the study is the percentage change in lumbar spine BMD at 12 months.

About Radius
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.

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.

Forward-Looking Statements
This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including the timing of Paladin's NDS and approval. These forward-looking statements are based on management's current expectations. These statements involve known and unknown risks and uncertainties that may cause our actual results, performance or achievements to be materially different from any expressed or implied by the forward-looking statements. These risks include, but are not limited to, the following: uncertainty regarding the results of regulatory submissions and oversight; success of our commercial operations; success of our clinical trials and preclinical studies; risks related to manufacturing, supply and distribution; success of any collaboration, partnership, license or similar agreements; achievement of milestones; receipt of royalties or other future contingent payments; ability to implement pricing increases. These and other important risks and uncertainties discussed in our filings with the Securities and Exchange Commission, or SEC, including under the caption "Risk Factors" in our Annual Report on Form 10-K for the year ending December 31, 2019 and subsequent filings with the SEC, could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. While we may elect to update such forward-looking statements at some point in the future, we disclaim any obligation to do so, even if subsequent events cause our views to change. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this press release.

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