MannKind and Vertice to Co-Promote Thyquidity™ (levothyroxine sodium) Oral Solution

December 17, 2020

WESTLAKE VILLAGE, Calif. and NEW PROVIDENCE, N.J., Dec. 17, 2020 (GLOBE NEWSWIRE) -- **MannKind Corporation (Nasdaq: MNKD) and Vertice Pharma** today announced that they have entered into a co-promotion agreement for Thyquidity™ (levothyroxine sodium) oral solution through MannKind's specialty sales force. THYQUIDITY is indicated as a replacement therapy in primary (thyroidal), secondary (pituitary), and tertiary (hypothalamic) congenital or acquired hypothyroidism. THYQUIDITY is not indicated for suppression of benign thyroid nodules and nontoxic diffuse goiter in iodine-sufficient patients or hypothyroidism during the recovery phase of subacute thyroiditis.

Under the terms of the agreement, MannKind's sales force will promote Thyquidity to adult endocrinologists, pediatric endocrinologists and other US healthcare providers who treat hypothyroidism. Vertice will make a specified quarterly payment to MannKind to defray the costs of the additional promotional activity and will pay MannKind royalties on gross profit resulting from all sales of Thyquidity.

"We are excited to co-promote Thyquidity with Vertice Pharma," said Michael Castagna, Chief Executive Officer of MannKind. "This arrangement allows us to strengthen our relationships with our current customers, expand into pediatric endocrinology and leverage the talent and capabilities of our sales force and reimbursement support systems."

"The team at Vertice Pharma is thrilled to be joining forces with MannKind to help launch our product to patients and healthcare providers," said Scott Meyers, Chief Executive Officer of Vertice Pharma. "I look forward to working with MannKind's commercial team to get ready for the launch of Thyquidity in 1Q 2021."

Hypothyroidism, also called underactive thyroid disease, is a common disorder in which the thyroid gland does not produce enough thyroid hormone. The prevalence of hypothyroidism is 4.6% in the US population.[1] Symptoms include fatigue, lethargy, cold intolerance, weight gain, constipation, change in voice, and dry skin.[2] Most patients require lifelong therapy to treat their hypothyroidism.[3]

INDICATION

Hypothyroidism
THYQUIDITY (levothyroxine sodium) oral solution is indicated as a replacement therapy in primary (thyroidal), secondary (pituitary), and tertiary (hypothalamic) congenital or acquired hypothyroidism.

Pituitary Thyrotropin (Thyroid Stimulating Hormone, TSH) Suppression
THYQUIDITY is indicated as an adjunct to surgery and radioiodine therapy in the management of thyrotropin-dependent well-differentiated thyroid cancer.

Limitations of Use

THYQUIDITY is not indicated for suppression of benign thyroid nodules and nontoxic diffuse goiter in iodine-sufficient patients, as there are no clinical benefits and over-treatment with THYQUIDITY may induce hyperthyroidism.

THYQUIDITY is not indicated for treatment of hypothyroidism during the recovery phase of subacute thyroiditis.

Important Safety Information

WARNING: NOT FOR TREATMENT OF OBESITY OR WEIGHT LOSS
Thyroid hormones, including THYQUIDITY, either alone or with other therapeutic agents, should not be used for the treatment of obesity or for weight loss. In euthyroid patients, doses within the range of daily hormonal requirements are ineffective for weight reduction. Larger doses may produce serious or even life-threatening manifestations of toxicity, particularly when given in association with sympathomimetic amines such as those used for their anorectic effects.

- THYQUIDITY is contraindicated in patients with uncorrected adrenal insufficiency.
- In the elderly and in patients with cardiovascular disease, THYQUIDITY should be initiated at lower doses than those recommended in younger individuals or in patients without cardiac disease. If cardiac symptoms develop or worsen, the THYQUIDITY dose should be reduced or withheld for one week and restarted at a lower dose.
- Patients with coronary artery disease who are receiving THYQUIDITY should be monitored closely during surgical procedures for cardiac arrhythmias. Monitor patients during concomitant administration of THYQUIDITY and sympathomimetic agents for signs and symptoms of coronary insufficiency.
- Use of oral thyroid hormone is not recommended in myxedema coma. Products formulated for IV administration should be used to treat myxedema coma.
- Patients with adrenal insufficiency should be treated with replacement glucocorticoids prior to initiating treatment with THYQUIDITY. Failure to do so may precipitate an acute adrenal crisis when thyroid hormone therapy is initiated.
- THYQUIDITY has a narrow therapeutic index. Regardless of the indication for use, careful dosage titration is necessary to avoid the consequences of over- or under-treatment.
- Addition of levothyroxine therapy in patients with diabetes mellitus may worsen glycemic control and result in increased antidiabetic agent or insulin requirements. Carefully monitor glycemic control after starting, changing, or discontinuing THYQUIDITY.

- Increased bone resorption and decreased bone mineral density may occur as a result of levothyroxine over-replacement, particularly in postmenopausal women. To mitigate this risk, patients receiving THYQUIDITY should be given the minimum dose necessary that achieves the desired response.
- Adverse reactions associated with THYQUIDITY therapy are primarily those of hyperthyroidism due to therapeutic overdosage.
- Many drugs and some foods affect thyroid hormone pharmacokinetics and metabolism and may alter the therapeutic response to THYQUIDITY. In addition, thyroid hormones and thyroid status have varied effects on the pharmacokinetics and actions of other drugs. Administer at least 4 hours before or after drugs that are known to interfere with absorption. Evaluate the need for dose adjustments when regularly administering within one hour of certain foods that may affect absorption. Prescribers should consult appropriate reference sources for additional information on drug or food interactions with THYQUIDITY.
- Closely monitor patients from birth to 3 months of age receiving THYQUIDITY due to the potential for glycerol- induced gastrointestinal irritation resulting in vomiting and/or osmotic diarrhea.
- THYQUIDITY should not be discontinued during pregnancy, and hypothyroidism diagnosed during pregnancy should be promptly treated. TSH levels may increase during pregnancy, so TSH should be monitored and THYQUIDITY dose adjusted as needed.

Please see: [https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/214047s000lbl.pdf] for full US Prescribing Information including Boxed Warning.

About MannKind Corporation

MannKind Corporation (Nasdaq: MNKD) focuses on the development and commercialization of inhaled therapeutic products for patients with endocrine and orphan lung diseases. MannKind is currently commercializing Afrezza® (insulin human) Inhalation Powder, its first FDA-approved product and the only inhaled ultra rapid-acting mealtime insulin in the United States, where it is available by prescription from pharmacies nationwide. MannKind is headquartered in Westlake Village, California, and has a state-of-the art manufacturing facility in Danbury, Connecticut. The Company also employs field sales and medical representatives across the U.S. For further information, visit www.mannkindcorp.com.

About Vertice Pharma

Vertice Pharma is a specialty pharmaceutical company focused on improving patients' health. Vertice Pharma develops, manufactures, markets, and distributes high-quality and affordable pharmaceutical products through its operating companies. Vertice Pharma has global headquarters in the United Kingdom and United States headquarters in New Jersey. For more information visit www.verticepharma.com.

Forward-Looking Statements

This press release contains forward-looking statements that involve risks and uncertainties. Words such as "believes," "anticipates," "plans," "expects," "intends," "will," "goal," "potential" and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon MannKind's current expectations. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties detailed in MannKind's filings with the SEC. For a discussion of these and other factors, please refer to MannKind's annual report on Form 10-K for the year ended December 31, 2019 as well as MannKind's other filings with the SEC. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this press release. All forward-looking statements are qualified in their entirety by this cautionary statement, and MannKind undertakes no obligation to revise or update any forward-looking statements to reflect events or circumstances after the date of this press release.

References

1. Hollowell JG, Staehling NW, Flanders WD, Hannon WH, Gunter EW, Spencer CA, Braverman LE. Serum TSH, T(4), and thyroid antibodies in the United States population (1988 to 1994): National Health and Nutrition Examination Survey (NHANES III). J Clin Endocrinol Metab. 2002 Feb;87(2):489-99. doi: 10.1210/jcem.87.2.8182. PMID: 11836274.
2. Chaker L, Bianco AC, Jonklaas J, Peeters RP. Hypothyroidism. Lancet. 2017;390(10101):1550-1562. https://pubmed.ncbi.nlm.nih.gov/28336049/
3. Jonklaas J, Bianco AC, Bauer AJ, et al. Guidelines for the treatment of hypothyroidism: prepared by the american thyroid association task force on thyroid hormone replacement. Thyroid. 2014;24(12):1670-1751. https://www.ncbi.nlm.nih.gov/pubmed/25266247.

Company Contact:

MannKind Corporation
818-661-5000
ir@mannkindcorp.com

Vertice Pharma
Kimberly Branch
kbranch@vistapharm.com
727-530-1633 x276

Source: MannKind