July 30, 2025

Kissei Pharmaceutical Co., Ltd.
(Code 4547, Tokyo Stock Exchange Prime Market)

Licensing Agreement with Viridian Therapeutics for "Veligrotug" and "VRDN-003" in Treatment of Thyroid Eye Disease

Kissei Pharmaceutical Co., Ltd. (Head Office: Matsumoto City, Nagano Prefecture; Chairman and CEO: Mutsuo Kanzawa; hereinafter "Kissei") announced that it has today entered into an in-licensing agreement with Viridian Therapeutics, Inc. (Head office: USA; President and CEO: Steve Mahoney; hereinafter "Viridian") regarding "veligrotug (generic name)" and "VRDN-003 (development code)", which are potential treatments for patients with thyroid eye disease (TED). Under this agreement, Kissei will acquire exclusive development and sales rights for veligrotug and VRDN-003 in Japan.

TED is an autoimmune inflammatory disease that affects orbital tissues, including the eyelids, lacrimal glands, extraocular muscles, adipose tissue, and other tissues surrounding the eye. It is mainly associated with thyroid dysfunction such as Graves' disease, although TED is a distinct disease that may still require treatment even if the underlying thyroid disease is well-controlled. Common symptoms include pain in and around the eye, conjunctival congestion and edema, and proptosis. In many moderate-to-severe cases, visual impairment such as decreased vision, diplopia, and visual field constriction occurs, significantly impairing the quality of life. It is broadly divided into active TED, in which symptoms progress (worsen) due to inflammation, and inactive TED, in which symptoms remain despite subsiding of inflammation. The pathophysiology of TED has been reported to involve the insulin-like growth factor IGF-1 receptor (IGF-1R) and thyroid-stimulating hormone receptor (TSHR). Both veligrotug and VRDN-003 are humanized monoclonal antibodies against IGF-1R, with VRDN-003 further engineered to have an extended half-life to enable a more sustained drug action. They are expected to alleviate inflammation of orbital tissues caused by autoimmune reactions and improve the symptoms of active and inactive TED by inhibiting the activity of IGF-1R. Viridian has completed pivotal global Phase III clinical trials for veligrotug and is preparing its biologics license application (BLA) in the United States. For VRDN-003, global Phase III clinical trials are currently being conducted. Veligrotug and VRDN-003 have not yet been developed in Japan, and will be developed by Kissei in the future.

Kissei has positioned the five-year medium-term management plan, "Beyond 80", which began in April 2025, as a period of growth investing and is working to expand its research and development pipeline. Through this agreement, Kissei will further strengthen its efforts in the areas of rare and intractable diseases and strive to contribute to the treatment of patients.

The upfront payment arising from this transaction has been incorporated into the consolidated earnings forecast for the fiscal year ending March 31, 2026, announced on July 29, 2025.

＜Reference＞

About Veligrotug

It is an intravenous humanized anti-IGF-1R antibody being developed by Viridian. In pivotal global Phase III clinical trials in patients with active and inactive TED conducted by Viridian, statistically significant improvement in symptoms such as exophthalmos and diplopia compared to the placebo group was demonstrated, and the drug was granted Breakthrough Therapy Designation by the United States Food and Drug Administration (FDA) in May 2025. Viridian plans to submit a BLA in the United States in 2H 2025.

About VRDN-003

It is a humanized anti-IGF-1R antibody that has the same IGF-1R binding domains as veligrotug and has been engineered to have an extended half-life to enable longer circulation in the body and potentially a significantly sustained drug action. Viridian is currently conducting global Phase III clinical trials of the drug as a self-administered subcutaneous injection in patients with active and inactive TED.

About Thyroid Eye Disease (TED)

TED is an autoimmune inflammatory condition affecting orbital tissues associated with thyroid dysfunction. It presents with various eye symptoms*, and in severe cases can cause diplopia and visual impairment, significantly impairing the quality of life. The incidence rate of TED is estimated to be 7.3 per 100,000 population (3.6 men and 13.0 women), with an estimated 34,913 patients in Japan. It has been reported that the underlying disease is Graves' disease in 70.8% of cases and Hashimoto's disease (chronic thyroiditis) in 9.4%.

*Pain in the eyes and surrounding areas, tearing, eyelid retraction, eyelid swelling, conjunctival congestion or edema, redness or swelling of the lacrimal papilla, exophthalmos, rabbit eyes, diplopia, decreased vision, visual field defects, Graefe's sign, ocular motility disorders, corneal disorders (erosion, ulcers, opacity, necrosis, perforation), optic neuritis, retinal disorders, etc.

(Diagnostic criteria and treatment guidelines for Graves' disease with malignant exophthalmos (thyroid eye disease) 2023 (Draft version 3))

About Graves’ disease

Graves' disease is an autoimmune hyperthyroidism characterized by the excessive production and secretion of thyroid hormones due to agonistic autoantibodies against the thyroid-stimulating hormone receptor (TSHR). The main clinical manifestations include symptoms of thyroid toxicosis such as tachycardia, weight loss, tremors of the fingers, and increased sweating, as well as diffuse thyroid enlargement and characteristic eye symptoms such as proptosis.

(Guidelines for the Diagnosis of Thyroid Diseases 2024)

About Insulin-like growth factor-1 receptor (IGF-1R)

Insulin-like growth factor (IGF) is a peptide hormone with a structure like insulin, mainly produced in the liver. It plays a role in regulating proliferation, survival, and the metabolism of substances including proteins in various cells. The insulin-like growth factor 1 receptor (IGF-1R) is a receptor-type tyrosine kinase that is activated by its ligand IGF-1, and plays critical roles to regulate cellular activities such as cell proliferation, differentiation, and inflammation.

About Thyroid-stimulating hormone receptor (TSHR)

Thyroid-stimulating hormone (TSH) is a glycoprotein hormone that acts on the follicular cells of the thyroid gland to promote the production and secretion of thyroid hormones. The thyroid-stimulating hormone receptor (TSHR) is located on the thyroid cell membrane and mediates the effects of TSH secreted from the pituitary gland. TSH regulates various functions and promotes the proliferation of the thyroid via TSHR.

About Viridian Therapeutics, Inc.

Viridian Therapeutics, Inc. (Nasdaq: VRDN) is a biopharmaceutical company focused on discovering, developing and commercializing potential best-in-class medicines for patients with serious and rare diseases.

For more information on Viridian, the Company's marketed products and pipeline of potential products, visit（https://www.viridiantherapeutics.com/）.