Rising to the Challenge of Satisfying Unmet Medical Needs

Eyeing Further Specialization

Back-of-the-eye Diseases

As a specialty company in the eye and other specific fields, we provide products and services to the prescription ophthalmic pharmaceutical market to satisfy a wide range of therapeutic needs, particularly front-of-the-eye diseases such as dry eye and glaucoma.

We have established ourselves as the No.1 ophthalmic pharmaceutical company in Japan.

We are now providing products and services for back-of-the-eye diseases, with the launch of EYLEA (aflibercept [genetical recombination]) in Japan to treat wet age-related macular degeneration (wet AMD).
The number of patients needing retinal disorder treatment is growing rapidly, driven by population aging and other factors.

Effective New Drugs Required for Underserved Back-of-the-Eye Field

There are unmet medical needs for many back-of-the-eye diseases, including wet AMD, diabetic retinopathy, and macular edema. Patients around the world live in the hope that groundbreaking new treatments will be developed. Overseas, retinal disorder markets are growing due to high unmet medical needs. Santen recognizes the strong potential in these markets to drive its growth going forward.

AMD involves abnormalities appearing in the macular area, a region located in the center of the retina that is vital for vision. It occurs in dry and wet forms. With wet AMD, abnormal blood vessels form below the retina in the macular area. Bleeding and leaking from these vessels cause retinal damage and functional impairment. Patients find it hard to see in the center of their vision, resulting in a sharp decline in Quality of Life (QOL).

Research has identified vascular endothelial growth factor (VEGF) as the substance that causes blood vessel formation and development and the leaking of blood and exudate. VEGF plays a vital role in the formation and maintenance of normal blood vessels, but it also triggers wet AMD by stimulating the development of unnecessary blood vessels.

Around 20 years ago there were no effective treatments for wet AMD, but there have been significant advances in therapeutic methods since then, including laser therapy, antibody drugs, and biopharmaceuticals. Due to the aging population and other factors, the Japanese market for retinal disorder treatments has grown at around 20% per annum and now accounts for approximately 10% of the total prescription ophthalmic pharmaceutical market.

Mechanism of Wet AMD

These illustrations are images.

In wet AMD, the macular area of the retina is damaged by bleeding and leaking from choroidal blood vessels, resulting in distortion and loss of central vision.
Helping patients in the retinal disorder field with the highest unmet needs as a specialized ophthalmic pharmaceutical company.

Providing a New Treatment Option for the Rapidly Increasing Number of Wet AMD Patients

Santen provides products and services to meet global therapeutic needs in the field of ophthalmology. Our mission is to help improve patients’ QOL. We have positioned back-of-the-eye diseases, including retinal disorders, as one of the highest priority areas where there are substantial unmet medical needs.

The back-of-the-eye disease AMD is the fourth most common cause of vision loss in Japan. Patient numbers are increasing sharply as the population ages, but only a small proportion of patients receive treatment. With few pharmaceutical options for the treatment of wet AMD, healthcare professionals have long hoped for new treatments to become available.

To broaden the treatment options available, Santen has launched EYLEA in Japan, a new treatment for wet AMD. As a specialized ophthalmic pharmaceutical company, we consider it extremely important to provide healthcare professionals with products needed by patients. Our goal is to continue supplying unique products, information, and services that satisfy patients’ unmet needs, in a bid to contribute to better treatment.
I Am Confident We Can Maximize EYLEA’s Product Value Through Partnership with Santen

Since it was first approved in the U.S. in 2011, EYLEA has been successfully marketed in Australia, Latin America, Europe and some other countries and regions. EYLEA has been well received in these markets, serving as a new treatment option that meets the therapeutic needs of patients around the world. In Japan, EYLEA has seen a smooth uptake in the market in just a few months after its launch, and now contributes to the treatment of many patients.

As a specialty company with an unshakeable No.1 share in the Japanese market for prescription ophthalmic pharmaceuticals, Santen is the ideal partner for us as we enter the field of ophthalmology. We feel assured and encouraged by the fact that Santen has established a strong relationship with some 13,000 ophthalmologists across Japan, as well as by the company’s in-depth understanding of the needs of the medical community. I am confident that our partnership with Santen will further accelerate the market penetration of EYLEA in Japan.

Dr. Carsten Brunn
President, Bayer Yakuhin, Ltd.
Sales Strategy
Leveraging Santen’s Strengths

Taking on the challenge of establishing a presence in a new treatment field based on relationships of trust with ophthalmologists across Japan.

Demonstrating Our Strengths as a Specialized Ophthalmic Pharmaceutical Company

*EYLEA* has penetrated the Japanese market much faster than expected. Immediately after launch, the drug was adopted by university hospitals and other facilities already using other intravitreal VEGF inhibitors. Santen’s sales in Japan in fiscal 2012 reached ¥3,183 million in only four months from launch. These strong results serve to highlight the significant unmet medical needs for wet AMD in Japan. We expect sales in fiscal 2013 to reach ¥9,852 million.

As well as *EYLEA*’s unique product profile, we attribute this success to our knowledge and expertise built up over many years in the field of ophthalmology and the close collaboration with our sales partner Bayer Yakuhin, Ltd. We have also developed relationships of trust with ophthalmologists over many years and have received feedback from many doctors on the need for a new therapeutic option for wet AMD.

*EYLEA* has penetrated the Japanese market extremely rapidly, even compared with overseas markets, and we feel that we have been able to meet the expectations of patients and healthcare professionals alike. Looking ahead, we will continue to strive to supply products and services to satisfy unmet medical needs so as to allow more patients access to therapies.

Takeshi Ito
Corporate Officer
Head of Prescription, Pharmaceuticals Sales Department,
Sales and Marketing Division, Prescription Pharmaceuticals
Creating Products for Unmet Medical Needs

Promoting global clinical development for creating products based on global medical treatment needs.

Developing Competitive New Drugs to Address Needs for Treating Retinal Disorders

In the Fiscal 2011–2013 Medium-Term Management Plan, Santen proposed a strategic objective of “promoting globally oriented research and development.” In addition to corneal disorders and glaucoma, areas where Santen has an especially strong presence, we have defined retinal disorders as a key area and are developing products to meet global medical needs in back-of-the-eye diseases.

DE-109 has been assigned orphan drug status by the regulatory authorities in the U.S. and Europe for the indication of non-infectious posterior uveitis. A project team has been formed in the U.S. that is managing the SAKURA1 Phase 3 global study at approximately 150 sites. DE-102 (betamethasone) is undergoing Phase 2/3 studies in Japan for the indication of macular edema associated with diabetes and BRVO2. Pre-clinical studies demonstrated sustained efficacy when injected around the affected area. Manufacturing methods are being developed for commercial-scale production, a partnership agreement has been signed with Oakwood Laboratories of the U.S., and we are making every effort to successfully develop this product as quickly as possible.

Through our experience of providing medical information and detailing for EYLEA, we are gaining an ever deeper understanding of treatment needs, including feedback on treatment methods and challenges with AMD and expectations for product development. We reflect on this feedback from patients and healthcare professionals on their experience with treatment methods and use this information when developing new pharmaceuticals to support better visual and physical health for patients around the world.

1. Study Assessing double-masked Uveitis Treatment
2. branch retinal vein occlusion

Message

I Have High Expectations for Santen’s Efforts in Retinal Disorders

Wet age-related macular degeneration (wet AMD) ranks as the fourth leading cause of acquired blindness in Japan. Around 10 years ago, the number of patients was estimated at approximately 330,000 people. But the number of patients has increased rapidly since then to double that number today due to aging and other factors. Treatment needs are thus rising.

Up to now, there were only two intravitreal VEGF (vascular endothelial growth factor) inhibitors that were effective in treating wet AMD. However, the launch of EYLEA has broadened treatment options, raising expectations for maintaining and improving patients’ sight. As a specialist, I am delighted that a new drug has been developed for retinal disorders where there are high unmet medical needs.

I hope that Santen will continue to draw on its knowledge as a specialized ophthalmic pharmaceutical company to develop more outstanding pharmaceuticals sought by patients.

Mitsuko Yuzawa, M.D.
Professor, Division of Ophthalmology, Department of Visual Sciences, Nihon University School of Medicine