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To those concerned

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Notification related to the Completion of the Phase II Clinical Study of the Ophthalmic Solution UF-021 (product name Ocuseva™) on Retinitis Pigmentosa (2)

Regarding the Phase II clinical study of the ophthalmic solution UF-021 (product name Ocuseva™) under development as a therapeutic drug for retinitis pigmentosa (note 1), we notified of the completion of the study the other day. We have summarized the detailed results of the study below.

- Description -

The Phase II clinical study (this study) of the ophthalmic solution UF-021 (product name Ocuseva™) for retinitis pigmentosa, a refractory disease for which there is currently no appropriate therapeutic drug, was conducted for the purpose of investigating the possibility of improvement of the visual function in the central part of the ocular fundus. The patients who participated in the study had retinitis pigmentosa that had progressed to the mid- to late-stage: a visual acuity of 0.5 or more even with a narrow visual field. The study was carried out at six institutions in Japan (Hirosaki University, Iwate Medical University, Chiba University, Juntendo University, University of Miyazaki, and YUKO WADA Eye Clinic).

This study is a multi-center study versus placebo (solution not containing any pharmacological agent) based on the Good Clinical Practice (GCP). The study was conducted as a randomized, double-blind, 3-group parallel, comparative study in which the ophthalmic solution UF-021 (Ocuseva™) was instilled one drop per time or two drops per time (5 minutes interval) twice a day in the morning and evening for 24 weeks.

The primary endpoint of efficacy in this study was the change in the mean retina sensitivity of the central 2 degrees of the ocular fundus measured with a MP-1 microperimeter (note 2), which can measure the same site under the same conditions every time. Additionally, for the secondary endpoints, retina sensitivity by Humphrey perimeter (10-2), visual acuity, contrast sensitivity, and health-related Quality of Life (QOL) using a questionnaire on visual function (VFQ-25) were evaluated.

A hundred and twelve patients cooperated in this study. The efficacy was evaluated in 109 cases: 33 cases in the placebo instillation group, 38 cases in the 1-drop-per-time UF-021 instillation group, and 38 cases in the 2-drops-per-time UF-021 instillation group. In the primary endpoint, the change in the retina sensitivity of the central 2 degrees after 24 weeks from the pre-treatment level (adjusted analysis) increased significantly in the positive direction in the following order: 2-drops-per-time group > the 1-drop-per-time group > the placebo group. The tendency toward positive change in the 2-drops-per-time group was seen from Week 4 of treatment. In additional analysis, the change in the retina sensitivity from the pre-treatment level by 4dB or more (improved or aggravated) was seen as improvement in 15.2% of subjects in the placebo group, 7.9% in the 1-drop-per-time group, and 18.4% in the 2-drops-per-time group, whereas the change was seen as aggravation in 21.2% in the placebo group, 15.8% in the 1-drop-per-time group, and 2.6% in the 2-drops-per-time group, showing a statistically significant lower number of aggravated cases in the 2-drops-per-time group, compared to the placebo

group.

The retina sensitivity measured with the Humphrey perimeter (10-2), which was a secondary endpoint, showed statistically significant improvement at Weeks 4 and 8 of treatment in the 2-drops-per-time group compared to the placebo group. And when the retina sensitivity measured with the Humphrey perimeter (10-2) was compared between pre-treatment and Week 24, it was found the sensitivity showed statistically significant improvement only in the 2-drops-per-time group (results of additional analysis).

In terms of “vision-related social function” (Q11. Because of your eyesight, how much difficulty do you have seeing how people react to things you say? Q13. Because of your eyesight, how much difficulty do you have visiting people in their homes, at parties, or in restaurants?), among the question items of VFQ-25, the scores after 24 weeks showed statistically significant improvements in the following order: 2-drops-per-time group > the 1-drop-per-time group > the placebo group. The inter-group comparison also showed a statistically significant improvement in the 2-drops-per-time group compared to the placebo group. And when compared between pre-treatment and Week 24, the total score of VFQ-25 was found to have improved statistically significantly only in the 2-drops-per-time group (results of additional analysis).

The main adverse effect to UF-021 was ocular irritation, which disappears several minutes after instillation.

Dr. Yukihiko Mashima, an ophthalmologist and the president of R-Tech Ueno, says “As an ophthalmologist, I have seen many patients who suffer from retinitis pigmentosa, but this is a disease no medications or treatments have yet been established. For this reason, I was thinking that I wanted to develop a therapeutic drug for this unmet medical need for the patients. Immediately after I joined with R Tech Ueno in April 2005, I made plans for the development of a therapeutic drug to treat retinitis pigmentosa. The Phase 1 clinical study of the ophthalmic solution UF-021 (product name Ocuseva™) was completed in 2008, and now I am very pleased with the results obtained in this Phase 2 clinical study. The results show the patients with aggravated central retina sensitivity could be significantly reduced in number. My goal is to obtain approval for this drug, Ocuseva, as quickly as possible so that it can be used to treat people who suffer from retinitis pigmentosa in the world. R-Tech Ueno is considering clinical development overseas of therapeutic drugs for unmet medical needs with our business partner Sucampo Pharmaceuticals, Inc. (note 4) for age-related macular degeneration (note 3) which is the leading cause of blindness in the U.S. in addition to retinitis pigmentosa.”

Hereafter, our company intends to release information at academic conferences, etc.

(note1) About Retinitis Pigmentosa

Retinitis pigmentosa is a hereditary disease and its prevalence rate is said to be about 1 in 5000 people in the world and 1 in 4000 - 8000 people in Japan. When this number is applied to the population of Japan, 128 million people, the number of patients with retinitis pigmentosa can be estimated as 16,000 - 32,000 people which makes this disease an orphan disease. On the other hand, when projecting the number of patients with retinitis pigmentosa in the world from the world population, 6.75 billion people (2008), it can be estimated as 1.35 million people. When retinitis pigmentosa progresses, patients suffer progressive night blindness, where it becomes difficult to see in dim light, or visual field constriction and then deterioration of vision. In the end stage, they may suffer from severe visual loss or even blindness. It is designated as an intractable disease and appropriate therapeutic drugs or therapeutic methods have not been established at the moment. According to the report by the “Research Study Group Regarding Retinochoroidal and Optic Atrophy”, a specified disease treatment research program of the Ministry of Health, Labour and Welfare (MHLW) in 2005, retinitis pigmentosa is the 3rd cause for impaired vision and especially in patients aged 60 or under it is the leading cause for impaired vision.

Accreditation of Retinitis Pigmentosa as a Specified Disease

Some diseases are very difficult to treat, they chronically develop, leave after-effects and make it extremely difficult or impossible for the patient to return to society, require a high medical cost, cause a heavy burden both domestically and mentally such as financial problems and nursing care and furthermore, as they are rare diseases they need to be studied on a nationwide scale. MHLW designates such diseases as intractable diseases. Currently, 130 diseases are designated as intractable diseases. Retinitis pigmentosa is a research target of the clinical research study area of the Research for Overcoming Intractable Diseases, MHLW. Disease number 33. Additionally, among the 130 intractable diseases, 56 are accredited as “specified diseases” and receive public

fund assistance for medical expenses. Retinitis pigmentosa is one of the “specified diseases” and is covered by public fund assistance for medical expenses. Diseases subsidized for medical expenses of designated intractable diseases: disease number 37.

Reference: Japan Intractable Disease Information Center www.nanbyou.or.jp/sikkan/114_i.htm

(note 2) About MP-1 Microperimeter

The MP-1 microperimeter combines a fundus camera and an automated perimeter. It can automatically measure the retina sensitivity of the measurement point set on the retinal fundus in advance. Tests can be conducted in the same measurement point of the retina as before therefore the retina sensitivity of the same region of the fundus can be measured time-dependently (the follow up function). The characteristics of this device is that as it has an automatic tracking function according to the eye movement, it can measure the retina sensitivity accurately of a certain point of the fundus by detecting and correcting slight deviations due to eye movements during tests (the auto tracking function).

(note 3) About Age-related Macular Degeneration

Age-related macular degeneration is a main causative disease of adventitious blindness in the U.S., Europe and Japan. In Japan, about 1 in 100 of the people aged 50 or over is affected by age-related macular degeneration (epidemiological study: Hisayama Study). In the U.S., currently about 2 million patients are suffering from severe impaired vision and it is said that the number of patients will increase to 3 million by 2020. In America and Europe, the dry (atrophic) form without new blood vessels is common where severe visual loss is induced by atrophy of the macular region. Currently, the patients take supplements however effective therapeutic drugs have not been developed yet.

(note 4) About Sucampo Pharmaceuticals, Inc.

Sucampo Pharmaceuticals, Inc. is a biopharmaceutical company located in Bethesda, Maryland, USA which focuses on the research and development and commercialization of pharmaceutical drugs based on prostones. The chairman and chief executive officer (CEO) of Sucampo Pharmaceuticals, Inc., Ryuji Ueno (physician, doctor of medicine, doctor of pharmacy), was the first person in the world to identify the potential of prostones, endogenous fatty acids, as pharmaceutical products. Sucampo Pharmaceuticals, Inc. was founded in 1996 by Dr. Ryuji Ueno and Dr. Sachiko Kuno, currently the advisor of the International Business Division.

In the U.S., Sucampo Pharmaceuticals, Inc. is marketing Amitiza® (lubiprostone) 24 mcg as a therapeutic drug for chronic idiopathic constipation in adults and Amitiza® 8 mcg as a therapeutic drug for irritable bowel syndrome with constipation in adult women. Sucampo Pharmaceuticals, Inc. is developing drugs for gastrointestinal disorders and age-related disorders with large potential markets and furthermore, targets disorders where many patients suffer without any sufficient therapeutic methods.

Homepage of Sucampo Pharmaceuticals, Inc.: [http:// www.sucampo.com](http://www.sucampo.com)

Amitiza® is a registered trademark of Sucampo Pharmaceuticals, Inc..

• About R-Tech Ueno, Ltd.

R-Tech Ueno is a bio venture company established in September 1989 for the purpose of marketing and R&D of drugs. Under leadership of the president, also a medical doctor, the company is developing new drugs on the theme “Physician-Oriented New Drug Innovation”, targeting ophthalmologic and dermatologic diseases that previously had no effective therapeutic agent.

We aim at becoming a “global pharmaceutical company specializing in specific fields (ophthalmology and dermatology) and selling and developing pharmaceutical products through the eyes of doctors.” We are promoting development of new drugs of unmet medical needs (medical needs that are not fulfilled yet) which the government recommends and assists, orphan drugs and the drugs in the field of anti-aging (lifestyle drugs).