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News & Information

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Notice of Agreement of License Term Sheet for PC-SOD in Europe.

We are pleased to announce that a European pharmaceutical company (hereinafter referred to as "European Partner") and our company have agreed on the outline of an exclusive license agreement (term sheet) in Europe regarding the development of PC-SOD (LT-1001) for the prevention of chemotherapy-induced complications, such as peripheral neuropathy (CIPN) and others.

We have been developing PC-SOD as a preventive drug for CIPN caused by oxaliplatin, one of the anticancer drugs. As already announced, based on the results of Phase II clinical trials in Japan, the implementation of Phase III clinical trials in Japan and its protocol were approved by Pharmaceuticals and Medical Devices Agency (PMDA), and preparations are currently underway. Meanwhile, for overseas development, our policy is to grant an exclusive license to an overseas pharmaceutical company for the development, registration for approval, and commercialization of our patents, and to entrust the development to the company. Therefore, we have been participating in conferences such as BIO USA and BIO EUROPE to look for partner companies.

As a result, European Partner, which had shown great interest in the development of the drug during our meetings at the conference, proposed licensing discussions with us, which continued for several months. During this time, we signed a confidential agreement, provided information on the results of the Phase II clinical trials in Japan, and answered a wide range of questions from European Partner. On the other hand, they interviewed prominent European physicians in the field and discussed the possibility of developing PC-SOD in Europe. As a result, they proposed a term sheet to us, based on their judgment that there is an extremely high clinical need for oxaliplatin-based CIPN prevention, and that PC-SOD has a good chance of being approved as the world's first drug for CIPN. As a result of repeated discussions between the two companies, an agreement of the term sheet has now been reached. Under the term sheet, our company

grants European Partner the exclusive right to develop, register for approval, and commercialize PC-SOD in Europe. In return, we will receive an upfront payment, development milestone payments (payments received as development progresses), sales milestone payments (payments received as sales exceed a certain amount), and royalties (a percentage of sales). All development in Europe, including clinical trials, will be conducted by European Partner and we will fully cooperate with European Partner.

European Partner and our company expect to conclude a final agreement by June 2025, by which time they will conduct various audits (due diligence) on LTT and PC-SOD. This term sheet is not legally binding, and the signing of the term sheet does not guarantee the conclusion of a final agreement.

We will report back as progress is made in this project.

PC-SOD (LT-1001) is a biopharmaceutical that uses our proprietary DDS technology and is a breakthrough new drug that can eliminate reactive oxygen species, which cause various diseases (there are no drugs with a similar mechanism of action in the world). CIPN, the target disease of this study, is a type of side effect associated with anticancer drug therapy, and is a major problem in clinical practice because it causes numbness and other symptoms after administration of anticancer drugs and interferes with cancer treatment. We have focused on the fact that there is no method (medicine) to prevent this side effect and that the cause of this side effect is reactive oxygen species (ROS), and have been developing PC-SOD for the prevention of CIPN.