



Progress Report of Collaborative Research with Astellas Pharma Inc.

Immuno-Biological Laboratories Co., Ltd (hereinafter “**IBL**”) and Astellas Pharma Inc. (“**Astellas**”, Headquarters: Chuo-ku, Tokyo, Japan; President and CEO: Yoshihiko Hatanaka) entered into a collaborative research agreement in relation to “drug applications using human protein produced by transgenic silkworms” on December 25, 2013. We have been conducting collaborative research with an aim to commercialize drugs using a valuable protein produced by transgenic silkworms. We are pleased to announce that we have successfully completed the fundamental reviewing process regarding the characteristics of the valuable protein in the first stage of this collaborative research. Now we are moving forward into the second stage.

Overview and Expected Timeline of Collaborative Research

Name of valuable protein: Human Fibrinogen

Timeline for commercialization

Stage	Details	Status
First stage (collaborative research)	Fundamental review of the characteristics of the valuable protein	Completed
Second stage (collaborative research)	Review manufacturing method with an aim for drug application.	Expected to be completed by the end of the financial year.
Enter the agreement of development for the drug application.	Conditions: A specific milestone is confirmed to be achieved through the completion of the collaborative research.	Discussion on entering agreement will be started after confirming that all the required conditions have been fulfilled.
Product release	Releasing drug that uses human fibrinogen as the material.	Targeted for 2020.

IBL and Astellas are aiming to realize a stable supply of reliable human fibrinogen produced through the use of transgenic silkworm production technology. The targeted release of this drug is 2020.

We developed a new production system in which a soluble protein can be effectively secreted in the cocoons of transgenic silkworms. In addition, we also developed groundbreaking technology for producing human fibrinogen with a high efficacy through our collaborative research with Nippon Flour Mills Co., Ltd.

Astellas is a R&D type global pharmaceutical company whose philosophy is “*Contribute toward improving the health of people around the world through the provision of innovative and reliable pharmaceutical products*”. This collaboration is the part of the realization of their business strategies for proactively utilizing external resources and investing in new fundamental technology. They have released information about the collaborative research on their website.

Note: A portion of the human fibrinogen research and development received funding under the outsourcing research project “Technology Development for Creating New Market by Utilizing Animal Genomes,” organized by the Ministry of Agriculture, Forestry and Fisheries between 2009 and 2011.

About Fibrinogen

Fibrinogen is major molecular blood coagulation and is used for tissue adhesion, tissue closing, and the halting of bleeding in surgical operations. The size of the global market for products containing fibrinogen is expected to grow to more than 100 billion yen in 2018 (Information Resource: Evaluate Pharma). Because fibrinogen is difficult to produce using by microorganisms due to its complex protein structure, fibrinogen derived from human blood is currently used for clinical practice.

Expected Outcome

IBL has successfully developed groundbreaking technology that can effectively produce human fibrinogen in the cocoons of transgenic silkworms. Because there is minimal risk of virus contamination of the human fibrinogen secreted from the cocoons, it makes possible to stably produce reliable supply of human fibrinogen in larger volumes.