

Innovation all for the patients



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Chugai and Nara Medical University Jointly Win the 4th Japan Bioindustry Award for Discovery and Development of Hemlibra for the Treatment of Hemophilia A

TOKYO, July 15, 2020 -- [Chugai Pharmaceutical Co., Ltd.](#) (TOKYO: 4519) announced that the company and Nara Medical University have jointly won the 4th Japan Bioindustry Award by Japan Bioindustry Association for “Therapeutic revolution for hemophilia A with development and discovery of the bispecific antibody-drug which can substitute the function of coagulation factor VIII.” In the project, Chugai collaborated with Department of Pediatrics at Nara Medical University, which is at the forefront of basic/clinical research on hemophilia in Japan. The award recognizes significant achievements which have greatly contributed to the development of bioindustry or for those expected to contribute to the field.

Hemlibra[®] is created based on Chugai’s idea that a bispecific antibody, which binds to two different antigens, substitutes the function of *in vivo* protein and treats hemophilia A. Having conducted an enormous number of experiments, Chugai discovered and developed a bispecific antibody as a new drug candidate. In the process of discovery and development, Chugai also developed its proprietary antibody engineering technology (ART-Ig[®]) to address issues in large-scale manufacturing of bispecific antibodies. In the course of evaluating bispecific antibodies, and designing and conducting clinical studies, Hemlibra has been launched as a pharmaceutical product in collaboration with Nara Medical University, based on the foundation and knowledge accumulated by the university over many years in hemophilia treatment and basic research. Hemlibra is now widely used for the treatment of hemophilia A across the world. The cumulative number of patients treated with Hemlibra globally has reached more than 6,500, and the drug has been approved in over 90 countries. The award was given in high appreciation based on the following points; 1) impact of its social significance to improve QOL of patients and their families, 2) potential value of the development of the antibody engineering technology with a wide range of possible applications, and 3) greatly successful industry-academia partnership that has resulted in commercialization of a product through long-term collaboration with academia.

“To create innovative drugs, the utilization of open innovation with partners, including academia, is indispensable for Chugai. We are very pleased that our long-term collaboration with Nara Medical University has been highly appreciated,” said Dr. Osamu Okuda, Chugai’s President and COO. “Our drug discovery research is a source of creating value for patients. We will continue to make every possible effort to contribute to patients across the world through innovation.”

“It is our greatest pleasure to jointly receive the 4th Japan Bioindustry Award with Chugai. When I first heard about the possibility of this bispecific antibody from Dr. Hattori in 2003, I was very excited because I thought that we might be able to solve various problems related to current treatments for hemophilia A all at once. Looking back on the path of our joint research, it is like a dream to see the current widespread use of the drug among patients across the world. Development of Hemlibra is also internationally recognized

as a historic accomplishment, along with the development of recombinant coagulation factor VIII products. We are very happy to have participated in the industrial-academic collaboration project originated in Japan,” said Dr. Midori Shima, M.D., Ph.D., Vice President (for Academic Affairs)/Dean, School of Medicine, Nara Medical University.

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| Prize name | The 4th Japan Bioindustry Award |
| Achievement | “Therapeutic revolution for hemophilia A with development and discovery of the bispecific antibody-drug which can substitute the function of coagulation factor VIII” |
| Prize winner | [Chugai] Dr. Takehisa Kitazawa, Head of Discovery Pharmacology Dept., Research Div. Dr. Kunihiro Hattori, Senior Fellow, Research Div. Dr. Tomoyuki Igawa, CEO, Chugai Pharmabody Research Pte, Ltd. [Nara Medical University] Dr. Akira Yoshioka, M.D., Ph.D., Professor Emeritus Dr. Midori Shima, M.D., Ph.D., Vice President (for Academic Affairs)/Dean, School of Medicine Dr. Keiji Nogami, M.D., Ph.D., Associate Professor, Department of Pediatrics |
| Commendation ceremony | Date: October 14 (Wed.), 2020 (tentative) Venue: PACIFICO Yokohama (during the session of BioJapan2020) Program: Commendation Ceremony and Commemorative Lecture Meeting, etc. |

About Hemlibra

Hemlibra is a bispecific monoclonal antibody, which was developed using Chugai’s proprietary antibody engineering technologies. The drug is designed to bind factor IXa and factor X. In doing so, Hemlibra provides the cofactor function of factor VIII in people with hemophilia A, who either lack or have impaired coagulation function of factor VIII^{1, 2)}. Hemlibra is approved in more than 90 countries, since the product has been approved for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients with hemophilia A (congenital factor VIII deficiency) with factor VIII inhibitors for the first time in the world by the U.S. Food and Drug Administration (FDA) in November 2017.

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Sources

- 1) Kitazawa, et al. Nature Medicine 2012; 18(10): 1570
- 2) Sampei, et al. PLoS ONE 2013; 8(2): e57479

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