

Kyowa Hakko Kirin and BioWa Obtain Successful Settlement of United States Patent Infringement Lawsuit against Aragen Bioscience and Transposagen

Tokyo, Japan and Princeton NJ, USA, March 22, 2018 --- Kyowa Hakko Kirin Co., Ltd. (Tokyo: 4151, President and CEO: Nobuo Hanai, "Kyowa Hakko Kirin"), an R&D-based life sciences company with special strengths in biotechnology, including antibody research and development, and BioWa, Inc. (Princeton, NJ, USA, President and CEO: Takeshi Masuda, "BioWa"), a wholly-owned subsidiary of Kyowa Hakko Kirin and the exclusive worldwide licensor of the proprietary therapeutic antibody technology POTELLIGENT[®], today announce that they successfully resolved their United States patent infringement lawsuit against Aragen Bioscience, Inc. (Aragen) and Transposagen Biopharmaceuticals, Inc. (Transposagen).

In October 2016, Kyowa Hakko Kirin and BioWa filed a lawsuit in the U.S. District Court for the Northern District of California against Aragen and Transposagen for patent infringement, seeking a permanent injunction relief and unspecified damages. In the suit, Kyowa Hakko Kirin and BioWa asserted, among other things, that Aragen and Transposagen infringed Kyowa Hakko Kirin's U.S. Patent Nos. 6,946,292, 7,425,446, and 8,067,232, which underlie Kyowa Hakko Kirin's award-winning POTELLIGENT[®] Technology and cover alpha-(1,6)-fucosyltransferase (FUT8) knockout host cell lines and afucosylated antibodies.

In April 2017, Aragen and Transposagen sought to challenge the validity of the three asserted patents by filing petitions for *inter partes* review (IPR) in the U.S. Patent and Trademark Office. The Patent Trial and Appeal Board (PTAB) declined to institute review, finding that Aragen and Transposagen had "not shown a reasonable likelihood that it would prevail in showing the unpatentability of at least one challenged claim" of the patents. The PTAB's decision is final and not appealable.

In March 2018, Kyowa Hakko Kirin and BioWa successfully settled its patent infringement claims against Aragen and Transposagen. While the details of the settlement are confidential, Aragen and Transposagen agreed to exit the relevant business and destroy any FUT8 knockout cell lines or materials. In agreeing that the patents were valid and enforceable, Aragen and Transposagen made a confidential payment to Kyowa Hakko Kirin to resolve the parties' dispute. A Stipulation of Dismissal with prejudice of all the parties' respective claims was filed with the Court, ending the entirety of the dispute.

Kenya Shitara, Ph.D., Executive Officer, Director of Legal and Intellectual Property Department of Kyowa Hakko Kirin, said, "we are very pleased to reach a successful end to this case that protects our patent rights and the substantial investment we made in our breakthrough POTELLIGENT[®] Technology. Our commitment to vigorously defending our intellectual property rights and respecting fair competition was vindicated. By protecting our patents, we also protected the innovations and discoveries that we worked hard to achieve and that allowed us to bring our important POTELLIGENT[®] Technology to the market."

Takeshi Masuda, President and CEO of BioWa, agreed, “this lawsuit shows the strength of our patent rights, which is licensed to dozens of leading antibody research and development companies. Our valuable POTELLIGENT® technology remains available through our licensing program, which allows access to our IP.”

The Kyowa Hakko Kirin Group companies strive to contribute to the health and well-being of people around the world by creating new value through the pursuit of advances in life sciences and technologies.

About Kyowa Hakko Kirin

Kyowa Hakko Kirin Co., Ltd. is a research-based life sciences company, with special strengths in biotechnologies. In the core therapeutic areas of oncology, nephrology and immunology/allergy, Kyowa Hakko Kirin leverages leading-edge biotechnologies centered on antibody technologies, to continually discover innovative new drugs and to develop and market those drugs world-wide. In this way, the company is working to realize its vision of becoming a Japan-based global specialty pharmaceutical company that contributes to the health and wellbeing of people around the world.

You can learn more about the business at: www.kyowa-kirin.com.

About BioWa

BioWa is a wholly-owned subsidiary of Kyowa Hakko Kirin. BioWa is the exclusive worldwide licensor of the POTELLIGENT® Technology for creating a superior antibody molecule with enhanced ADCC, and COMPLEGENT® Technology for that with enhanced Complement-Dependent Cytotoxicity (CDC). The AccretaMab® platform consists both of POTELLIGENT® and COMPLEGENT® Technologies. BioWa has been offering POTELLIGENT® / COMPLEGENT® Technologies and the AccretaMab® platform to partners under a license to maximize the value of these technologies. Together with Kyowa Hakko Kirin, BioWa is committed to promoting ADCC/CDC enhanced monoclonal antibody-based therapeutics to fight against life-threatening and debilitating diseases.

For more information about BioWa, visit its website at www.kyowa-kirin.com/biowa.

About POTELLIGENT® Technology

POTELLIGENT® Technology improves potency and efficacy of antibody therapeutics by enhancing antibody-dependent cellular cytotoxicity (ADCC), one of the major mechanisms of action for antibody therapeutics. POTELLIGENT® Technology involves the reduction of the amount of fucose in the carbohydrate structure of an antibody using a proprietary fucosyltransferase knockout CHO cell line as a production cell. Research shows that POTELLIGENT® Technology dramatically enhances ADCC activity of an antibody *in vitro*, and significantly increases potency and efficacy of the antibody *in vivo*. A number of POTELLIGENT® antibodies are currently being investigated in human clinical trials.

As of today, POTELIGEO® (mogamulizumab), an antibody against chemokine receptor-4 (CCR4) using POTELLIGENT® Technology, has been approved for patients with

relapsed or refractory CCR4-positive adult T-cell leukemia-lymphoma (ATL), and for relapsed or refractory CCR4-positive peripheral T-cell lymphoma (PTCL) and cutaneous T-cell lymphoma (CTCL) in Japan. Kyowa Hakko Kirin has submitted its marketing authorization application to the European Medical Agency (EMA) and its Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for mogamulizumab to treat CTCL in patients who have received at least one prior systemic therapy, and has been granted Priority Review status in the US.

In addition, AstraZeneca and its global biologics research and development arm, MedImmune, a BioWa partner, have received regulatory approvals by the EMA, the FDA and the Japanese Ministry of Health, Labour and Welfare (MHLW) for Fasentra™ (benralizumab), an antibody against interleukin-5 alpha receptor using POTELLIGENT® Technology for severe eosinophilic asthma. These milestone events represent critical validation points for the POTELLIGENT® Technology.