

Fujifilm Kyowa Kirin Biologics and Mylan EPD Announce Launch of “Adalimumab (Genetical Recombination) [Adalimumab Biosimilar 1]” in Japan

PITTSBURGH and TOKYO – February 15, 2021 – Fujifilm Kyowa Kirin Biologics Co., Ltd. and Mylan EPD G.K., a company of the Viatriis group, today announced that “Adalimumab (Genetical Recombination) [Adalimumab Biosimilar 1]”, a biosimilar to AbbVie’s Humira® (Adalimumab (Genetical Recombination)), the top-selling drug in the world*, has launched in Japan. This is the first launch of a biosimilar to Humira® in Japan. Mylan EPD G.K. is in charge of the commercialization.

Sun-A Kim, Country Manager, Viatriis Japan said, “We are very proud to offer Adalimumab, a biosimilar to the world’s top-selling biologic medication Humira®, to patients in Japan. Today’s launch of Adalimumab, in partnership with Fujifilm Kyowa Kirin Biologics, is yet another testament to the power of Viatriis’ unique Global Healthcare Gateway® which helps partners like Fujifilm Kyowa Kirin Biologics with strong scientific expertise to further expand patient access to more affordable medicines in more markets around the world, including here in Japan, by leveraging Viatriis’ unmatched global infrastructure and regulatory expertise. Viatriis strives to be a Partner of Choice™ for companies seeking to empower more people worldwide to live healthier at every stage of life. With one of the industry’s largest and most diverse global biosimilars franchises, Viatriis is committed to improving patient access to Adalimumab and other critically important biologic medicines as well as providing more affordable treatment options for the patient we serve.”

“We are excited to be launching the first Adalimumab biosimilar in Japan, which has obtained approvals in major market regions of the world; EU, US, Canada and Japan,” said Atsushi Matsumoto, Fujifilm Kyowa Kirin Biologics President and CEO. “We are delighted to partner with Viatriis, whose significant experience and expertise in regulatory commercialization supports our commitment to contribute to increasing the treatment options for the patients with inflammatory conditions as well as saving healthcare costs. We continue to make all efforts to deliver high quality and affordable biosimilar products throughout the world.”

Fujifilm Kyowa Kirin Biologics and Viatriis entered into a partnership in 2018 for the commercialization of the product as Hulio® in Europe and Viatriis has commercialized the product in more than 20 countries across the region. In 2019, Fujifilm Kyowa Kirin Biologics and Viatriis expanded the partnership globally. Furthermore, Hulio® received market approval in the United States in 2020 and will be marketed by Viatriis in July 2023 pursuant to its patent license agreement with AbbVie.

Brand name	Adalimumab BS Subcutaneous Injection 40mg Syringe 0.8mL [FKB]	Adalimumab BS Subcutaneous Injection 40mg Pen 0.8mL [FKB]	Adalimumab BS Subcutaneous Injection 20mg Syringe 0.4mL [FKB]
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Generic name	Adalimumab (Genetical Recombination) [Adalimumab Biosimilar 1]	
Indications	<p>Rheumatoid Arthritis (including prevention of structural damage of joints)</p> <p>The following diseases inadequately controlled by existing therapies:</p> <p>Polyarticular-course Juvenile Idiopathic Arthritis</p> <p>Psoriasis Vulgaris, Arthritic Psoriasis, Pustular Psoriasis, Ankylosing Spondylitis, Entero-Behcet's Disease</p> <p>Remission induction and maintenance therapy for moderately or severely active Crohn's Disease (limited in case of inadequate response to existing therapies)</p>	Polyarticular-course Juvenile Idiopathic Arthritis
Market Approval date	June 29, 2020	
Listing date of the standard drug price	November 25, 2020	

**Humira had brand sales of approximately \$26.9billion globally for the 12 months ending December 2019, according to IQVIA.*

About Fujifilm Kyowa Kirin Biologics

Fujifilm Kyowa Kirin Biologics was established by FUJIFILM Corporation (President: Kenji Sukeno; hereinafter "Fujifilm") and Kyowa Kirin Co., Ltd. (President and CEO: Masashi Miyamoto, hereinafter "Kyowa Kirin") on March 27, 2012 as a company for developing, manufacturing, and marketing biosimilars.

By merging the technologies in advanced production, quality control and analysis which Fujifilm has developed over many years through its photographic film business, with the proprietary technologies and know-how which Kyowa Kirin has accumulated through its biopharmaceutical R&D and manufacturing, Fujifilm Kyowa Kirin Biologics creates revolutionary production processes and reduces costs for the production of biosimilars. Through this partnership, the company will develop and manufacture reliable, high quality, cost-competitive biosimilar products and commercialize these products in a timely manner. With this strategy, Fujifilm Kyowa Kirin Biologics aims to hold a leading position in the expanding biosimilar market.

You can learn more about the business at: fujifilmkyowakirin-biologics.com

About Viatris

Viatris Inc. (NASDAQ: VTRS) is a new kind of healthcare company, empowering people worldwide to live healthier at every stage of life. We provide access to medicines, advance sustainable operations, develop innovative solutions and leverage our collective expertise to connect more people to more products and services through our one-of-a-kind Global Healthcare Gateway®. Formed in November 2020 through the combination of Mylan and Pfizer's Upjohn business, Viatris brings together scientific, manufacturing and distribution expertise with proven regulatory, medical and commercial capabilities to deliver high-quality medicines to patients in more than 165 countries and territories. Viatris' portfolio comprises more than 1,400 approved molecules across a wide range of therapeutic areas, spanning both non-communicable and infectious diseases, including globally recognized brands, complex generic and branded medicines, a growing portfolio of biosimilars and a variety of over-the-counter consumer products. With a global workforce of approximately 45,000, Viatris is headquartered in the U.S., with global centers in Pittsburgh, Shanghai and Hyderabad, India. Learn more at viatris.com and investor.viatris.com, and connect with us on [Twitter at @ViatrisInc](https://twitter.com/ViatrisInc), [LinkedIn](#) and [YouTube](#).

In Japan, Viatris Pharmaceuticals Japan Inc, Pfizer UPJ G.K., Mylan EPD G.K., and Mylan Seiyaku, Ltd. are the companies of the Viatris Group.

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