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KYOWA HAKKO BIO RECEIVES FDA NO QUESTION LETTER FOR GRAS NOTICES ON HUMAN MILK OLIGOSACCHARIDES

Tokyo, Japan - November 30th, 2023 - KYOWA HAKKO BIO CO. LTD. (Kyowa Hakko Bio), a subsidiary of Kirin Holdings Company, Limited, is pleased to announce that it has received a no question letter from the United States' Food and Drug Administration (FDA) regarding its Generally Recognized as Safe Substances (GRAS) notices for three human milk oligosaccharides (HMOs). This no question letter from the FDA allows the use of Kyowa Hakko Bio's 2'-Fucosyllactose (2'-FL), 3'-Sialyllactose sodium salt (3'-SL), and 6'-Sialyllactose sodium salt (6'-SL) in non-exempt infant formula and various conventional foods (GRN 1051, GRN 1052, GRN 1053, respectively).

Kyowa Hakko Bio has been at the forefront of HMO research and development since 1990s, becoming the world's first company to establish a mass production system for these essential substances in 2000¹. Building on this groundbreaking achievement, the company successfully commenced commercial production of Kyowa Hakko Bio's HMOs (2'-FL, 3'-SL, 6'-SL) at its state-of-the-art facility in Thailand last year. Kyowa Hakko Bio is excited to expand the availability of these innovative ingredients successively in countries and regions where the necessary applications have been approved.

1) Tetsuo Endo et. al., *Appl. Microbiol. Biotechnol.* 53, 257-261 (2000)

Human milk oligosaccharides are complex carbohydrates naturally found in human breast milk, and they represent the third most abundant solid component after lactose and lipids and more than 200 types of HMOs have been found in breast milk. Since they are rarely found in cow's milk or milk derived from other mammals, and are particularly abundant in human colostrum, they are known to play a crucial role in supporting infant health and development. The market for infant formula containing HMOs is growing continuously in Europe and the United States, and consumption is expected to expand in China and Southeast Asia, where populations are expected to grow. CAGR is expected to be around 20% to 30%² in the future.

2) Barclays, "HMOs the next frontier of Infant Formula innovation," March 2022

"We are thrilled to receive the no question letter from the FDA for our GRAS notices on these important human milk oligosaccharides," said Yuki Kanzaki, the President & CEO of Kyowa Hakko Bio. "Receipt of this letter is a testament to our commitment to providing safe and innovative solutions for infant formula and conventional food manufacturers. We believe that the introduction of our HMOs will offer significant health benefits to infants and consumers worldwide."

Kyowa Hakko Bio remains dedicated to advancing the field of human milk oligosaccharide research and



development, continuously exploring new applications and benefits for these remarkable substances. The company is committed to working closely with regulatory authorities around the world to pursue the highest standards of safety and efficacy.

About Kyowa Hakko Bio CO., LTD. (Kyowa Hakko Bio)

Kyowa Hakko Bio CO., LTD. is a subsidiary of Kirin Holdings Company, Limited, and a leading company in the research, development, and production of innovative bioactive ingredients. With a strong commitment to scientific excellence and customer satisfaction, Kyowa Hakko Bio specializes in the development and production of amino acids, nucleic acids, and fermentation-derived ingredients, including human milk oligosaccharides. The company's mission is to contribute to the well-being of people around the world by providing high-quality, safe, and effective ingredients for various industries, including healthcare, pharmaceuticals, food, and cosmetics.

We strive to contribute to the health and well-being of people around the world
by creating new value through the pursuit of advances of life sciences and technologies.