



## Specified Clinical Trial on the Effects of $\beta$ -lactolin in Mild Cognitive Impairment (MCI)

— Collaborating with Hamamatsu City and Seirei Social Welfare Community  
to contribute to solving challenges in a rapidly-aging society —

**TOKYO, Tuesday September 30, 2020** Kirin Holdings Company, Limited (Kirin Holdings) started a specified clinical trial for people with mild cognitive impairment (MCI) using milk-derived  $\beta$ -lactolin\*<sup>1</sup>, a Kirin proprietary material, as part of a joint research project with Seirei Social Welfare Community (Seirei) in cooperation with Hamamatsu City, Shizuoka Prefecture in September 2020.

1 GTWY (glycine-threonine-tryptophan-tyrosine) peptide of tetrapeptide among  $\beta$ -lactopeptides containing tryptophan-tyrosine sequence.

Kirin established the Hamamatsu Wellness Lab\*<sup>2</sup> in February 2020 in cooperation with Hamamatsu City, and the medical institutions, universities, and participating companies in the city, and has since been working through empirical research to help prevent illness, and to care for and promote the health of the general public with a view to achieve the goal of “Wellness City Hamamatsu” A joint study is now being conducted with Seirei, which operates several medical and welfare facilities in Hamamatsu and other cities, to investigate the effects of  $\beta$ -lactolin on cognitive functions and mood states in people with MCI.

2 Refer to *The Hamamatsu Wellness lab Established in Hamamatsu, Shizuoka Prefecture*  
[https://www.kirinholdings.co.jp/news/2020/0218\\_01.html](https://www.kirinholdings.co.jp/news/2020/0218_01.html) (Japanese)

With a focus on epidemiological studies on the intake of dairy products and the prevention of dementia, Kirin has conducted research on the effects of dairy products on cognitive functions. In 2015, through joint research with the University of Tokyo,  $\beta$ -lactolin, an ingredient derived from milk that improves cognitive functions, was discovered, which has made it possible to develop readily consumable food products with this ingredient added\*<sup>3</sup>. It was also discovered through joint research with Keio University and others in 2019 that continuous  $\beta$ -lactolin ingestion improves memory and cognitive functions in healthy middle-aged and older adults\*<sup>4</sup>.

3 Title: Novel lactopeptides in fermented dairy products improve memory function and cognitive decline  
Authors: Yasuhisa Ano, Akihiko Takashima, Hiroyuki Nakayama, et al. Publication: *Neurobiology of Aging*  
DOI: 10.1016/j.neurobiolaging.2018.07.016. <https://pubmed.ncbi.nlm.nih.gov/30176402/>

4 Title: Supplementation with Whey Peptide Rich in  $\beta$ -Lactolin Improves Cognitive Performance in Healthy Older Adults: A Randomized, Double-Blind, Placebo-Controlled Study  
Authors: Masahiro Kita, Satoshi Umeda, Yasuhisa Ano, et al. Publication: *Frontiers in Neuroscience*  
DOI: 10.3389/fnins.2019.00399 <https://pubmed.ncbi.nlm.nih.gov/31068787/>  
Reference: *World first! A human study confirms milk-delivered  $\beta$ -lactolin improves memory.*  
[https://www.kirin.co.jp/company/news/2019/0425\\_02.html](https://www.kirin.co.jp/company/news/2019/0425_02.html) (Japanese)

### ● Research overview

Evaluate the impact of  $\beta$ -lactolin on MCI by assessing the cognitive functions and mood states of Hamamatsu residents determined to have MCI who take  $\beta$ -lactolin-containing supplements or a placebo on a continuous basis.

- (1) Participant recruitment period: September 2020 to August 2021
- (2) Eligible participants: Females/males of 50 years of age or older with MCI symptoms (80 participants planned)
- (3) Method: Ingest supplements containing  $\beta$ -lactolin or placebo supplements for 24 weeks.
- (4) Details of assessment: Before and after the ingestion period, a cognitive function test, profile of mood state (POMS) survey, QOL survey, blood test and olfaction test will be performed in addition to the MCI checkup provided by Seirei Social Welfare Community.

### ● Research objectives

Examine the effects of continuous  $\beta$ -lactolin ingestion on the cognitive functions and mood states in MCI. The results and findings obtained will be used to develop solutions for maintaining brain health through everyday living, which will further contribute to educational activities to raise awareness of brain health among the residents of Hamamatsu.