



March 9, 2016
Denka Company Limited
Denka Seiken Co., Ltd.

Denka Group Promotes Health Care in China via Heart Disease Risk Marker sd LDL-C

BEIJING STRONG BIOTECHNOLOGIES Obtains Beijing FDA Approval for the Production and Sale of a Diagnostic Reagent for the Measurement of the sd LDL-C Heart Disease Risk Marker

Denka Company Limited (headquarters: Chuo-ku, Tokyo; president: Shinsuke Yoshitaka; hereinafter “Denka”) hereby announces that BEIJING STRONG BIOTECHNOLOGIES, INC. (hereinafter “BSBE”¹), secured Beijing Food and Drug Administration (hereinafter “BFDA”) approval for the production and sale of a diagnostic reagent that measures the level of small, dense LDL cholesterol (hereinafter “sd LDL-C”²) in blood. Small, dense LDL cholesterol is a widely recognized risk marker³ for heart disease and coronary heart disease (CHD). Prior to this product, no diagnostic reagents for measuring sd LDL-C had been approved in China.

BSBE is a China-based company that produces in vitro diagnostic reagents serving as a strategic partner of Denka Seiken Co., Ltd. (headquarters: Chuo-ku, Tokyo; president: Tetsuro Maeda; hereinafter “Denka Seiken”), a core Denka Group operating company that produces influenza vaccines and various diagnostic reagents. Denka Seiken is the first in the world to develop a reagent for measuring sd LDL-C, which is used with automated diagnostic analyzers.

This diagnostic reagent has now been BFDA approved through BSBE with Denka Seiken’s technological assistance. Small, dense LDL cholesterol is designated as a target risk marker under the “863 program”.⁴ The “863 Program”⁴ aims to stimulate the development of advanced technologies in a wide range of fields and is operated under the auspices of the Chinese government.

In China, the demand for lipid panel examination⁵ is expected to grow, with an estimated total of 500,000,000 patients⁶ to undergo testing in 2020. Having obtained BFDA approval, BSBE is now better positioned to promote health and prevent diseases in China. By promoting sd LDL-C analysis as a part of preventive health care items, such as lipid panel examinations and risk assessments,⁷ BSBE may help reduce China’s rising medical costs.

As the supplier of essential raw materials for the new diagnostic reagent, Denka Seiken will help BSBE promote this diagnostic method in China. Simultaneously, efforts are now under way to obtain U.S. FDA marketing approval for Denka Seiken’s reagent for measuring sd LDL-C. Denka Seiken will continue to develop diagnostic reagents that measure various lipoprotein subclasses⁸ linked to lifestyle-related diseases as well as biomarker diagnostic reagents. Thus, Denka Seiken will continually promote health and prevent diseases around the world.

In line with the Denka100 growth strategy management plan, Denka has focused its management resources on “healthcare” as a new growth driver to develop next-generation products. Moving forward, Denka will strive to meet society’s expectations by actively addressing market needs and solving the challenges confronting our customers.

For inquiries:

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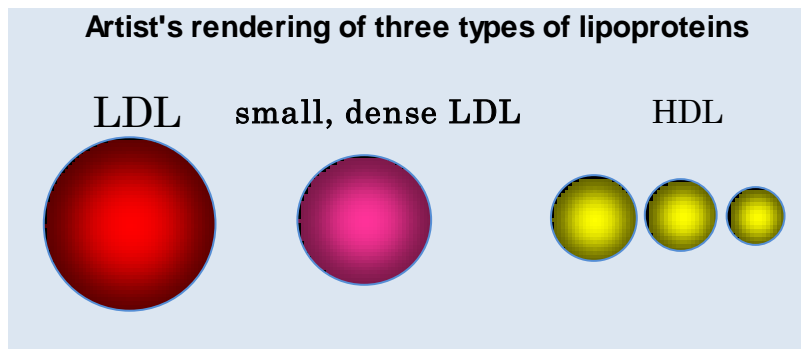
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(1) Company name	BEIJING STRONG BIOTECHNOLOGIES, INC. (BSBE)
(2) Main business	Production and sale of in vitro diagnostic reagents for clinical use and biochemical examination equipment
(3) Established	March 29, 2001 (Listed on Hong Kong's Growth Enterprise Market since October 2014; Stock code: 300406)
(4) Headquarters	Beijing, China
(5) Representatives	President: Zou Zuojun Ph. D.
(6) Capital	249,837,313 Chinese yuan (Approx. ¥4.7 billion)
(7) Employees	Approx. 280
(8) Operating results*	Net sales: 508,274,000 Chinese yuan (Approx. ¥9.6 billion) Net income: 210,641,000 Chinese yuan (Approx. ¥4.0 billion) Total assets: 1,186,532,000 Chinese yuan (Approx. ¥22.5 billion)

*Results for the fiscal year ending December 31, 2014

2. Small, dense LDL cholesterol: A lipoprotein with a comparatively small particle size and high density relative to ordinary LDL. The new diagnostic reagent is used to measure the density of sd LDL in the overall cholesterol count.



Currently, our studies show that knowing the sd LDL-C level has the following clinical significance:

- (1) The density of sd LDL-C is closely related to the risk of CHD development.
- (2) Even when LDL cholesterol levels are low, a high sd LDL-C density exposes patients to greater risk of CHD development.
- (3) sd LDL-C measurements may provide useful markers for monitoring users of such lipid lowering drugs as statins and fibrates.
- (4) A number of studies indicate a relationship between sd LDL-C levels and metabolic syndrome, the accumulation of visceral fat and high blood pressure as well as the aggravation of diabetes and arterial sclerosis.

3. Risk marker: A factor that suggests an increased probability of disease development.
4. The 863 program: Formulated by four Chinese researchers in March 1986, this program was approved by the State Council of the People's Republic of China as a National High-Technology R&D Program targeting nine priority technological fields.
5. Lipid panel examination: A test of blood serum lipid content that includes measurements of substances such as HDL and LDL cholesterol as well as triglycerides.
6. The estimated number of lipid panel tests administered as part of regular health checkups as calculated by Global Industry Analysts Inc. and posted on *CHOLESTEROL TESTING 2012*
7. Risk assessments: Diagnoses based on examination results of the risk of future disease development
8. Lipoprotein subclasses: Detailed classifications of lipoproteins based on density, particle size and proportion of components