August 23, 2017
Denka Company Limited
Denka Seiken Co., Ltd.

Denka Group Receives U.S. FDA 510k Clearance for an In-vitro Diagnostic Reagent for the Measurement of Coronary Heart Disease Risk Marker sd LDL-C, Making Progress in Its Key Life Innovation Business

Denka Company Limited (headquarters: Chuo-ku, Tokyo; president: Manabu Yamamoto; hereinafter "Denka") hereby announces that Denka Seiken Co., Ltd. (headquarters: Chuo-ku, Tokyo; president: Mitsukuni Ayabe; hereinafter "Denka Seiken"), a core Denka Group operating company, has received 510k clearance from the U.S. Food and Drug Administration (FDA) for an in-vitro diagnostic reagent that measures the level of small, dense LDL cholesterol (hereinafter "sd LDL-C"[1]) in blood. Aiming to initiate the production and sale of this reagent, which was designed for use with automated chemical analyzers, Denka Seiken submitted for premarket notification (510k) and the product was cleared as in-vitro diagnostic reagent on August 18, 2017 (U.S. time).

Well aware of usefulness of sd LDL-C as an excellent risk marker[2] for coronary heart disease (CHD), Denka Seiken drew on its proprietary technologies to develop the reagent that measures sd LDL-C for use with automated clinical chemistry analyzers while submitting marketing approval applications to relevant authorities in countries around the world. In China, our strategic partner BEIJING STRONG BIOTECHNOLOGIES, INC. secured Beijing Food and Drug Administration approval for the reagent in March 2016.

In the United States, following the submission for FDA premarket notification in June 2016, we received inquiries from said authority in August of that year and again in March 2017. Based on the time it took to address these inquiries, we expected clearance to be granted around March 2018 and made an announcement to this effect in a press release dated April 28, 2017. However, thanks to the swift progress of the FDA examination, our submission was cleared for 510k earlier than expected.

While to date the measurement of LDL cholesterol has been insufficient as a risk indicator for heart disease and CHD, the measurement of sd LDL-C

promises to serve as an accurate risk indicator. At the same time, despite sd LDL-C being one of a number of the lipoprotein subclasses[3] that comprise LDL cholesterol, a special method had to be devised to measure it. With the aim of popularizing diagnosis based on sd LDL-C measurement, Denka Seiken applied its highly sophisticated diagnostic reagent technologies to develop the reagent so that it could be employed in commonly used automated clinical chemistry analyzers.

Currently, heart disease is the No. 1 cause of death in the United States. Accordingly, we are convinced that the creation of a simple, quick and low-cost diagnostic solution for assessing heart disease risk will promote the maintenance of good health, help prevent disease and reduce medical expenses for people in the United States.

Today, an estimated 2,000 million lipid panel examinations take place every year in countries around the world. At the same time, a growing number of people are suffering from lifestyle-related diseases, including those attributable to abnormal lipid metabolism, reflecting such factors as changes in diet. Denka Seiken, having obtained U.S. FDA 510k clearance for this reagent for sd LDL-C measurement, is determined to launch the full-scale marketing of this and other reagents for measuring lipoprotein subclasses in the United States and China. Simultaneously, Denka Seiken will engage in initiatives to raise public awareness regarding heart disease and to help increase the number of institutions that provide relevant examination. We will thus popularize the sd LDL-C measurement as part of multi-faceted efforts aimed at contributing to people's well-being.

The impact of U.S. FDA 510k clearance on profits for the fiscal year ending March 31, 2018, will be minor. However, we expect the new diagnostic reagent to make a significant contribution to profits in the subsequent fiscal year and beyond.

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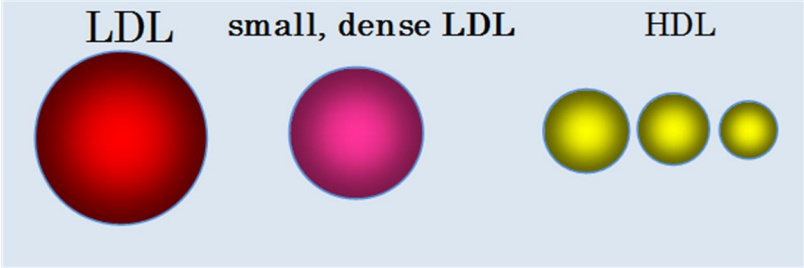
1. A lipoprotein with a comparatively small particle size and high density relative to ordinary LDL. The new diagnostic reagent is used to measure the density of sd LDL in the overall cholesterol count

Artist's rendering of three types of lipoprotein



Currently, our studies indicate 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 developing CHD.
(2) Even when LDL cholesterol levels are low, a high sd LDL-C density exposes patients to greater risk of developing CHD.
(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.

2. A factor that suggests an increased probability of disease development.

3. Detailed classifications of lipoproteins based on density, particle size and proportion of components.