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Denka Company Limited
Denka Seiken Co., Ltd.

Progress in Obtaining U.S. FDA Approval for a Diagnostic Reagent for the Measurement of Heart Disease Risk Marker sd LDL-C and in the Denka Group's Key Life Innovation Business

Denka Company Limited (headquarters: Chuo-ku, Tokyo; president: Manabu Yamamoto; hereinafter "Denka") hereby announces the current status of its efforts to obtain approval from the U.S. Food and Drug Administration (FDA) for the production and sale of a diagnostic reagent that measures the level of small, dense LDL cholesterol (hereinafter "sd LDL-C"[1]) in blood. The Group is aiming for the full-scale U.S. launch of the reagent, which was designed for use with automated diagnostic analyzers by Denka Seiken Co., Ltd. (headquarters: Chuo-ku, Tokyo; president: Mitsukuni Ayabe; hereinafter "Denka Seiken"), a core Denka Group operating company, and Denka Seiken is the first in the world to develop this diagnostic reagent. To that end, in June 2016 Denka Seiken applied for an in-vitro diagnostic reagent approval. Details are as follows.

After submitting the application in June 2016, Denka Seiken received inquiries from the FDA in August of that year with regard to the content of clinical data. Having completed the delivery of the requested information to the FDA in February 2017, Denka Seiken was given to believe that the potential benefits to patients of a means of measuring their sd LDL-C levels were better understood by the agency.

However, further inquiries were made in March 2017, requiring the submission of more detailed clinical data. Furthermore, since the U.S. diagnostic guidelines for heart diseases were revised in 2007, during the period in which the clinical trials for this diagnostic reagent (1998 – 2011) were undertaken, FDA officials requested the reanalysis of a portion the existing data in order to ensure that the new guidelines retrospectively apply to evidence gleaned before said revision and that the objectivity of our clinical evaluation would never be questioned.

Although such reanalysis is expected to have no substantial impact on the conclusion of our clinical research because it affects only a small volume of data, Denka Seiken understands that the FDA's requests must be honored and fulfilled and therefore agreed to the execution of said reanalysis.

As clinical trials for the sd LDL-C measurement utilize specimen materials stored at public healthcare institutions in the United States, the reanalysis of data needs to be partially commissioned to external institutions. Given the situation, and taking into account the time needed for the preparation of reports based on the results of reanalysis, Denka Seiken currently expects approval to be granted around March 2018.

An active producer of influenza vaccines and various diagnostic reagents, Denka Seiken is the first in the world to develop a diagnostic reagent for use with automated diagnostic analyzers for the measurement of sd LDL-C, a widely recognized risk marker[2] for heart disease and coronary heart disease (CHD). In March 2016, Denka Seiken acquired Beijing Food and Drug Administration approval for the production and sales of this diagnostic reagent, thereafter launching the product in China. In Japan, efforts are now under way to cultivate potential markets for this product in the field of annual health checkups.

Going forward, Denka Seiken will continue to develop diagnostic reagents that measure various lipoprotein subclasses[3] linked to lifestyle-related diseases as well as biomarker diagnostic reagents, with the aim of promoting health management and disease prevention around the world.

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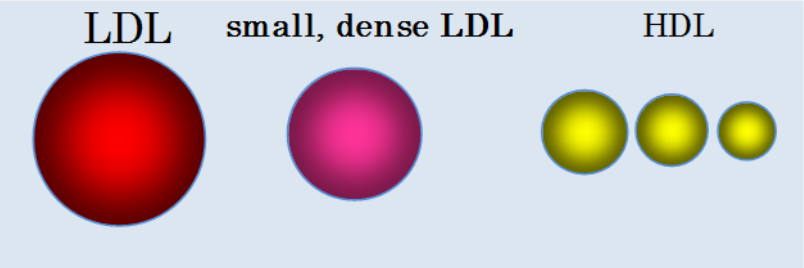
1. A lipoprotein with a comparatively small particle size and high density relative to ordinary LDL. The new diagnostic reagent is used to measure the density of sd LDL in the overall cholesterol count.

Artist's rendering of three types of lipoprotein



Currently, our studies 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.

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.