

**FOR IMMEDIATE RELEASE**

**Successful Identification of Metabolite Differences in Urine  
between Healthy, Breast Cancer and Colorectal Cancer Groups**

*Aim to establish technology for simple & easy-to-use cancer screening*

**Tokyo, June 14, 2016** --- Hitachi, Ltd. (TSE: 6501; “Hitachi”), Summit Pharmaceutical International Corporation and Sumitomo Corporation (collectively “Sumitomo Corporation Group”) today announced the successful development of basic technology for a new cancer screening technique that distinguishes between urine samples from patients with breast or colorectal cancer and healthy people, based on a comprehensive analysis of urine metabolites. The technique detects over 1,300 metabolites such as sugar and lipids from one urine sample, identifies about 10 candidate biomarkers\*<sup>1</sup> specific to cancer, and by examining the difference in the amount of biomarkers, is able to distinguish urine samples from the cancer patients. The next step will be a further study of the correlation between cancer type and the candidate biomarkers in order to establish a simple and easy-to-use urine-based cancer screening test, as part of efforts to contribute to a healthier and prosperous society.

This research is partially supported by “Acceleration Transformative Research for Medical innovation (ACT-M),” from the Japan Agency for Medical Research and Development, AMED.

In Japan, the growing cost of social security due to an aging society and low birthrate has become a major societal issue. Apart from the significant personal distress and challenges from developing cancer, a recent study by the National Institute of Public Health has reported that the economic cost of the disease including both the direct cost of diagnosis and treatment as well as the indirect cost of lost labor could become as large as 10 trillion Japanese yen per year.\*<sup>2</sup> Thus to control healthcare costs as well as to prevent the early loss of labor in a decreasing working population, early detection and treatment of cancer is important. For the patient however currently available methods represent a time-consuming and expensive process as biomarker-based cancer screening, most commonly blood tests, require the patient to visit a medical facility, and there is still no established test that will cover the full range of cancers. Further, regions where there is a sparsity of medical facilities present even more obstacles to early detection and treatment as it may be difficult to receive necessary medical examination.

To address this need, Hitachi focused on a developing a simple and convenient urine test where the patient themselves could collect the sample, and has been conducting basic research to establish a new cancer screening method and process. With the cooperation of Sumitomo Corporation Group, Hitachi conducted an extensive analysis of metabolites in urine from cancer and non-cancer patients, and found that there was a clear difference between the amount of certain metabolites found in cancer and non-cancer patient urine samples. Using these metabolites as candidate biomarkers, the principle component analyses (PCA)<sup>\*3</sup> indicated that it was possible to distinguish between urine samples from breast cancer, colorectal cancer and non-cancer patients using the volume of candidate biomarkers in the urine.

The results of this study open the possibility of a new style of cancer screening which increases screening opportunity as the patients themselves are able to collect urine samples and receive testing by sending the samples to a medical or clinical laboratory. Hitachi and Sumitomo Corporation Group will continue to study the molecular structure of these candidate biomarkers, and proceed with research to distinguish other types of cancers apart from breast and colorectal cancer, for the practical application of this technology.

#### **Details of the research results**

- 1) About 10 candidate biomarkers identified from among over 1,300 metabolites found in urine

A comprehensive analysis of urine metabolites was conducted using high-resolution liquid chromatograph/mass spectrometer<sup>\*4</sup> on commercially available urine samples with information on age, sex and the presence of cancer for 3 groups: breast cancer, colorectal cancer and healthy subjects. Focusing on the difference between hydrophilic<sup>\*5</sup> and hydrophobic nature of metabolites in optimizing the measurement conditions, over 1,300 metabolites were detected from each urine sample, over twice as many than previously detectable.

- 2) Differentiated healthy and cancer patients from urine samples using PCA

When the metabolites contained in the urine from the 3 groups were compared, a large difference in the presence of certain metabolites was found. These metabolites were then used as candidate biomarkers to differentiate breast cancer and colorectal cancer patient urine samples, and PCA was conducted. The results indicated that it was analytically possible to distinguish between urine samples from healthy persons, breast cancer and colorectal cancer patients.

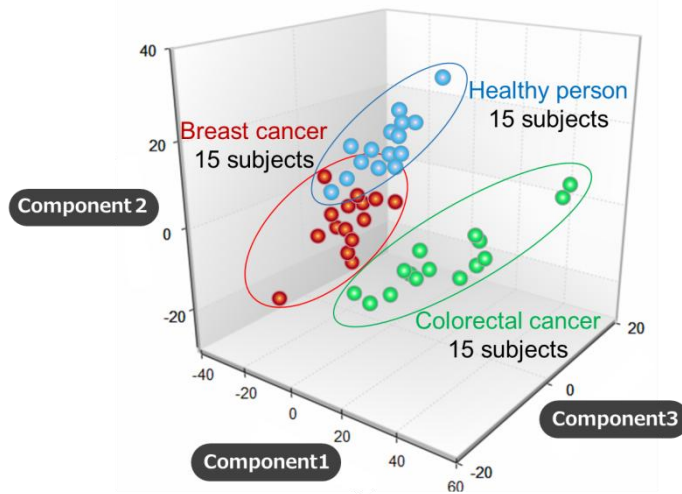


Figure. PCA comparison from healthy, breast cancer, colorectal cancer groups

- \*1 Biomarker (biological marker): a measurable biological characteristic often used in medical examinations to indicate a particular biological state.
- \*2 Source: National Institute of Public Health, Japan (NIPH) study on the medical and economic value of cancer treatment (in Japanese), posted on the Japan Cancer Society website.
- \*3 Principal component analysis (PCA): a statistical technique to emphasize variation and identify strong patterns in a dataset.
- \*4 Liquid Chromatograph/Mass Spectrometer: highly sensitive analytical equipment to analyze a liquid mixture. The components in the liquid are separated using a liquid chromatograph, followed by detection with a mass spectrometer.
- \*5 Hydrophilic: a term used to describe affinity to water, for example, materials that dissolve easily in water. Hydrophobic is the opposite characteristic, that of having little or no affinity to water, for example, materials that do not easily mix or dissolve in water.

### **About Hitachi, Ltd.**

Hitachi, Ltd. (TSE: 6501), headquartered in Tokyo, Japan, delivers innovations that answer society's challenges. The company's consolidated revenues for fiscal 2015 (ended March 31, 2016) totaled 10,034.3 billion yen (\$88.8 billion). The Hitachi Group is a global leader in the Social Innovation Business, and it has approximately 335,000 employees worldwide. Through collaborative creation, Hitachi is providing solutions to customers in a broad range of sectors, including Power / Energy, Industry / Distribution / Water, Urban Development, and Finance / Government & Public / Healthcare. For more information on Hitachi, please visit the company's website at <http://www.hitachi.com>

**About Summit Pharmaceuticals International Corporation**

Summit Pharmaceuticals International Corporation (SPI) plays a central role in the medical science business line as a group company of Sumitomo Corporation(see below). SPI provides high-quality integrated products and services to pharmaceutical industry, from research equipment and bioresources for drug discovery, pharmaceutical licensing and research alliance support, to manufacturing of APIs, intermediates for pharmaceuticals, generic drugs and biologics.

Leveraging our close connections to Japanese pharmaceutical manufacturers and academia, we help partners who work with us in aims of expanding business in Japan and Asia based on solid partnership.

**About Sumitomo Corporation**

Sumitomo Corporation is a leading global trading company with 110 locations in 66 countries and 23 locations in Japan. The entire Sumitomo Corporation Group consists of nearly 900 companies and more than 70,000 personnel. The SC business is continuously expanding into a diverse range of products and services. Its core business units are Metal Products, Transportation & Construction Systems, Environment & Infrastructure, Media, Network, Lifestyle Related Goods & Services, Mineral Resources, Energy, and Chemical & Electronics.

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