



**PRESS RELEASE**

August 19, 2014

## Aiming at the Ideal Cancer Treatment

# The Shizuoka Cancer Center Launches the Study on Personalized Medicine Utilizing Multiomics-Based Patient Evaluation Technology

The Shizuoka Cancer Center launched the new clinical research named “Project HOPE(High-Tech Omics-based Patient Evaluation)” (led by the principal investigator Ken Yamaguchi, president of the SCC) in collaboration with SRL, Inc. (Managing Director: Masashi Ogawa) in January, 2014.

The Project HOPE is to evaluate diathesis and cancer characteristics of each patient by multiomics-based analyses, which integrate genomics, transcriptomics, proteomics and metabolomics.\*1 Evaluation results are to be used for research and development of new cancer diagnosis and treatment technologies. At the same time, “mibyō” medicine\*2, or presymptomatic medicine in English implying medicine to treat a condition in which an illness has not yet manifested itself but may develop into an illness later, is to be promoted, using results from genomics on patients’ diatheses. Analytical results and samples are stored for each patient, which will be employed for their personalized medicine when new evaluation technologies or treatments are developed in the future. This implies the features of the project well, as the whole multiomics-based analyses can be done within one single research institute, having clinical sites with capacity for collecting and storing data for many years to come. This is a research plan in accordance with “Ethical Guidelines for Human Genome and Genetic Analysis Research” revised in 2013 covering patients who agree on participating the research, with the approvals of ethical review boards at the SCC and SRL.

For the Project HOPE, about one third of the patients taking surgeries to remove cancers at the SCC are considered as eligible participants, who can supply with fresh and enough quantity of cancer tissues. DNA sequencing on exons\*3 (whole exon sequences) and genetic expressions of entire genes are analyzed together first, and then, DNA sequencing on blood cells is analyzed as a sample of healthy tissues. The research focuses on how to utilize these data (gene characteristics) for the future medical care of each patient. If and when necessary, comprehensive analyses on protein and metabolites can be added (Fig. 1). About 500 patients have participated in this research for the past six months since the launch of the project. This is a good pace for the project to achieve the goal of analyzing 3,000 cases in the 3-year period.

The duty allocation for the project is that the SCC is responsible for medical care of patients, collecting clinical data, gene analysis, and collating clinical data and gene information, and SRL is responsible for development of simplified analytical technology, accuracy control and research for clinical test innovation.

## **The Purposes and the Clinical Significance of the Project HOPE**

The purposes of this project are as follows: “Promoting personalized medicine,,” “practicing mibyop(resymptomatic) medicine,” “providing learning experiences for medical staff and researchers” and “research and development.”

For the first purpose “promoting individualized cancer treatment,” gene mutations and abnormal gene expressions, which can be highly considered as being relevant to proliferation and progress of cancer, have already been identified in 74% of the initial 220 clinical cases. The percentage is expected to be higher as the accuracy of analysis is being improved. With these data in hand, clinical oncologists will be able to know the tumor characteristics of each patient, and to make the best choice of molecular targeted drug depending on the character of tumor in case of future recurrence.

Furthermore, the results obtained from this research are to be stored long preparing for the future. This is one of the features of the multiomics-based patient evaluation, which enables the data to be utilized for the future diagnosis technology and choice of molecular targeted drugs for the benefit of patient.

Secondly, “practicing mibyop medicine” means to know the genetic information of a patient’s diathesis from the results of blood cell analysis, which represents the normal tissue, to foresee the risk of acquiring disease originated in such habits as drinking alcohol and to utilize it for preventive medicine. By acquiring such information, pathogenesis of hereditary cancer syndromes or any other inheritable diseases can be foreseen and can be taken care of by preventive therapy, which is also beneficial for patient’s family. In the project HOPE, one case of hereditary cancer and four cases of inheritable gastrointestinal disorder and heart disease have been discovered so far, and have been treated by specialists with supports from genetic counselors. Genetic analysis of normal tissue is thus effective for practicing “mibyop medicine,” which revives an ancient Chinese idea of “mibyop” saying “a good doctor treats an illness before symptoms manifest themselves” in modern medicine.

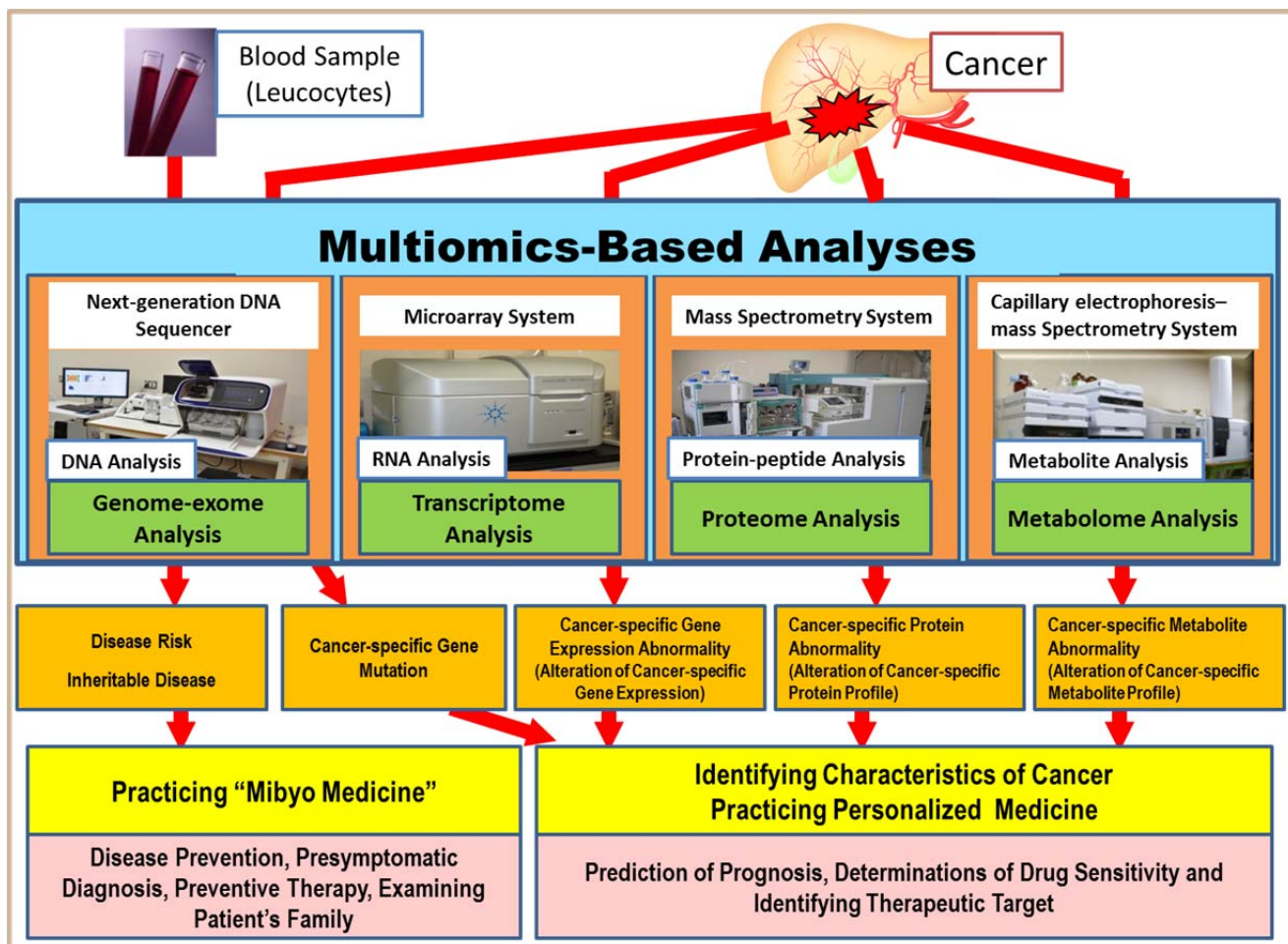
For the third purpose “providing learning experiences for medical staff and researchers,” it should be noted that medical staff at the SCC treat patients after having learned about genetic changes of their cancers and diatheses. This does not only contribute to the improvement of cancer treatment, but also helps the medical staff to master genomic medicine. Meanwhile, the researchers in charge of analyses have chances to heighten the analysis accuracy from collating the analysis results with the clinical data. Therefore, they can learn about how genetic changes are related to clinical conditions more in detail, and as a result, clinical tests based on gene analyses will be more widely known and accepted in the society.

From the perspective of the fourth purpose “research and development,” the accomplishments of the project HOPE can make important “seeds” for research and development of progressed cancer treatment. It is expected that new genetic changes, which will be likely to result in developing new molecular targeted drugs, biomarkers and diagnostic agents. In the future, research and development based on the accomplishments of the project HOPE will be further promoted as a collaborative research among the SCC, the Pharma Valley Center and SRL under the banner of “the Pharma Valley Project” promoted by Shizuoka Prefecture.

The outline of this project will be presented at the press conference titled "Opening the Way to the New Era for the Medical Health Industry: The Latest Accomplishments and Research Facilities of the Shizuoka Pharma Valley Project" scheduled to be held on Tuesday, August 26, 2014 in Tokyo. Also at the 73<sup>rd</sup> Annual Meeting of the Japanese Cancer Association, nine titles are going to be presented at the Poster Presentation for the day two.

**Comments about How Much is Expected for the Project HOPE, by Ken Yamaguchi, M.D., Ph.D., the president of the Shizuoka Cancer Center**

The Project HOPE is a research pursuing the ideal cancer treatment, which gives back the benefits of the multiomics-based cancer analysis technology accumulated in the world over the past decades to each patient. This is a research carried out at one hospital, in which entire exon and entire gene expression analyses are done as long as samples are obtained from patients taking surgeries there, and the results of the analyses are immediately collated with the clinical data. It is so unique as not to be seen in other parts of the world. Moreover, it is also new and unique that hereditary diatheses of patients, which are brought out by this research, are to be utilized for "mibyō" (presymptomatic) medicine. At the same time, it is expected that the data obtained from this research may bring forth some new medical technologies for fully curing as many cancer patients as possible.



\*1 Mibyo Medicine: It's the idea quoted from a book entitled "The Yellow Emperor's Classic of Internal Medicine," which was written almost 20 centuries ago during the Han Dynasty and is considered as the oldest book of medicine in China. The idea still has a significance even in modern medicine, as it focuses on preventing disease by treating a patient "during presymptomatic stage" with sophisticated modern medical technologies. The idea also encourages early detection and treatment of disease.

\*2 Multiomics-based Analyses: A comprehensive method analyzing objects responsible for human body functions, not piece by piece but in the whole. "-mics" is a suffix for an encompassing analysis, as it makes genomics, transcriptmics, proteomics and metabolomics, depending on what is being analyzed.

\*3 Exon: Genome encodes all of human genetic information, and has a string-like structure consisting of 3 billion base pairs known as DNA. It's a cluster of 21,000 genes spreading all along, which carries the cell's genetic information and hereditary characteristics. The part in the genetic structure containing information on protein composition is called exon, which consists of about 60 million base pairs corresponding to about 2% of the whole genomic base pairs. Most of genetic mutation responsible for cancer is considered as exon abnormality on about 500 cancer-related genes.

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### **Shizuoka Cancer Center**

Since April, 2002, the Shizuoka Cancer Center has been serving as a medical center specialized in cancer treatment, offering all the advanced medical technologies including endoscopic surgery, operation support robot called "da Vinci" and proton-beam therapy. The SCC aims at the ideal cancer treatment and values the patients' perspectives, always trying to be close to patients and their families and to give whole-person treatment including mental care. It has been officially designated as a special functioning hospital and a core medical institute for cancer treatment in Shizuoka Prefecture, with 589 beds including 50 in two palliative care units. The SCC also serves as a core facility of the Pharma Valley Project, recruiting new medical equipment or ideas clinically demanded for better medical care and bringing forth new products through the Pharma Valley Center in collaboration with medical industries.

### **SRL, Inc.**

SRL, Japan's largest commercial laboratory with its net sales of approx. ¥100 billion (FY 3/2014), provides comprehensive clinical laboratory testing services to medical institutions including universities and national hospitals and it continued to expand market by targeting major hospitals nationwide. SRL has established a framework capable of providing clinical laboratory testing services across all testing fields, from general and emergency testing to esoteric and research testing, through its regional laboratories and group companies.

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