



Current Agreements

Dealdoc

Collaboration agreement for cardiac safety studies in Japan

iCardiac Technologies

SNBL CPC

Sep 07 2016

Collaboration agreement for cardiac safety studies in Japan

Companies:	iCardiac Technologies SNBL CPC
Announcement date:	Sep 07 2016
Deal value, US\$m:	n/d

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Details

Announcement date:	Sep 07 2016
Industry sectors:	Diagnostic Research tools Services
Therapy areas:	Cardiovascular
Deal components:	Collaborative R&D
Stages of development:	Phase I

Financials

Deal value, US\$m:	n/d
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Termsheet

iCardiac Technologies, Inc., a market and innovation leader in cardiac safety and respiratory studies, and SNBL CPC Japan, an experienced and reputable Site Management Organization (SMO) in Japan, have announced that they will collaborate on cardiac safety studies in Japan.

The collaboration will involve both Thorough QT (TQT) studies as well as QT assessment in Phase I studies.

It will also enable CPC Clinical Trial Hospital of Medipolis Medical Research Institute, a highly experienced Phase I site, which SNBL CPC Japan has been supporting, to offer iCardiac's advanced High Precision QT and Early Precision QT analysis methodologies to its sponsors.

The companies will partner to further educate the Japanese pharmaceutical market on scientific and regulatory changes enabling QT assessment as part of Phase I studies.

The agreement stems from recent developments involving iCardiac's central role in conducting a validation study demonstrating the reliability of using QT data obtained from Phase I studies.

This approach of using Phase I data for regulatory decision-making, which enables an alternative path to conducting a TQT study, was approved in December 2015 by the International Council for Harmonisation.

Press Release

September 7, 2016, Rochester, N.Y. and Tokyo, Japan—iCardiac Technologies, Inc., a market and innovation leader in cardiac safety and respiratory studies, and SNBL CPC Japan, an experienced and reputable Site Management Organization (SMO) in Japan, have announced that they will collaborate on cardiac safety studies in Japan.

The collaboration will involve both Thorough QT (TQT) studies as well as QT assessment in Phase I studies. It will also enable CPC Clinical Trial Hospital of Medipolis Medical Research Institute, a highly experienced Phase I site, which SNBL CPC Japan has been supporting, to offer

iCardiac's advanced High Precision QT and Early Precision QT analysis methodologies to its sponsors. The companies will partner to further educate the Japanese pharmaceutical market on scientific and regulatory changes enabling QT assessment as part of Phase I studies. The agreement stems from recent developments involving iCardiac's central role in conducting a validation study demonstrating the reliability of using QT data obtained from Phase I studies. This approach of using Phase I data for regulatory decision-making, which enables an alternative path to conducting a TQT study, was approved in December 2015 by the International Council for Harmonisation. Since then, Japanese regulators have approved a TQT waiver for an iCardiac customer.

"We are honored to be working with SNBL group, a preeminent provider of clinical trials services. iCardiac has been at the forefront of developing, validating, and popularizing the use of early QT data as an alternative to doing a TQT study, and we are extremely pleased to have a partner to offer these advanced services in the Japanese market," said Alex Zapesochny, President & CEO of iCardiac Technologies.

Hisao Nakajima, President of SNBL CPC Japan, echoed, "We are also honored to introduce into Japan the advanced QT assessments developed by iCardiac. SNBL group is very pleased to serve our clients, pharmaceutical companies, for efficient drug development through the new cardiac safety technologies stemming from this collaboration."

About iCardiac Technologies:

iCardiac Technologies, Inc. is an industry-leading centralized core laboratory for cardiac safety and respiratory services. Its high precision cardiac safety assessment methodology has set a new standard for precision and accuracy in all phases of clinical trials. The company serves 8 of the top 10 global pharmaceutical companies, as well as numerous small and mid-sized pharma and biotechnology firms. For more information, please visit: www.icardiac.com.

About SNBL Clinical Pharmacology Center, Ltd. and Shin Nippon Biomedical Laboratories Ltd:

SNBL Clinical Pharmacology Center, Ltd. (SNBL CPC Japan) has provided site management services for clinical trials, as site management organization (SMO) in Japan for over 15 years. It is a wholly owned subsidiary of Shin Nippon Biomedical Laboratories, Ltd. (SNBL), a listed public company on Tokyo Stock Exchange. For more than 55 years, SNBL has been a leader in helping biopharmaceutical companies generate high-quality data with the exceptional precision needed to rapidly advance new medical therapies and innovations that improve patients' lives. Today, SNBL has operations in Japan, the United States, China, and Cambodia, with headquarters in Tokyo, Japan.

Filing Data

Not available.

Contract

Not available.