

Announcement of the agreement on the collaborative development of the
Electronic source data (“e-Source data”) system for clinical studies
with ACRONET Corporation

OncoTherapy Science, Inc. (President & CEO: Takuya Tsunoda; hereinafter, “OncoTherapy”) announces that OncoTherapy and ACRONET Corporation (Head office: Bunkyo-ku, Tokyo; President and CEO: Koichi Kato; hereinafter, “ACRONET”) agreed on the collaborative development of the electronic source data (“e-Source data”) system (hereinafter, “Platform”), which is currently under development by ACRONET, and signed into the agreement today. OncoTherapy will contribute the improvement of its value and receive the benefit as compensation according to the contribution.

ACRONET, a contract research organization (CRO) and a subsidiary of ITOCHU Corporation, is developing the electronic data source system for clinical trials by use of the information technology (IT) and know-how in the multiple categories of industries including medicals. On the other hand, OncoTherapy conducts multiple clinical trials of the novel cancer drugs, peptide-based cancer vaccine, antibodies and small molecule drugs domestically and internationally on its own, and also contributes to the academic clinical research by providing the drug products to the investigator initiated clinical trials.

The collaborative development by these two companies is expected to contribute to the speed-up and streamline of the clinical trials.

The effect of this collaboration to the earnings forecast of 2013 fiscal year is immaterial.

<Electronic source data (“e-Source data”) system >

The electronic system related to the clinical trials in which the clinicians directly input the clinical information to the tablet computers instead of the paper-based medical record. While the utilization of the EDC (electrical data capture) has been attempted for efficient operation of clinical studies, further streamlining using the electrical source data system (hereinafter “the system”), in which the electrical data can be used as source data, has also been promoted. This system enables sponsors of clinical studies to access the clinical information at the same time as the data input and is expected to improve the efficiency and reduce the amount of cost. Since the publication of the draft guidance for the system published in 2012 and the recommendation from U.S. Food and Drug Administration (FDA) on the utilization of the system, introduction of the system has been promoted rapidly. The promoted introduction of the system is also predicted in Japan.

<ACRONET Corporation>

ACRONET Corporation, which was established in 2003 and became a subsidiary of ITOCHU corporation in 2005, is a contract research organization which undertakes monitoring, data management, statistical analysis, and writing clinical study report.

- Company name: ACRONET Corporation
- Head office: 1-4-1, Koishikawa, Bunkyo-ku, Tokyo
- Representative: President & CEO, Koichi Kato
- Business lineups: Contract services for clinical studies such as monitoring, data management, statistical analysis and writing clinical study reports. Development of electrical case report form (CRF) system and providing the function as a data centre.
- Capital: 100 million yen