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Approval of Additional Indication of Ultrasound Contrast Agent SONAZOID® for Injection

TOKYO, Japan (August 10, 2012) – Daiichi Sankyo Co., Ltd. announced today that it has received approval in Japan for an additional indication for the ultrasound contrast agent, 16μL vials of SONAZOID® for injection, for the imaging of focal breast lesions.

SONAZOID® is an ultrasound contrast agent consisting of microbubbles with increased stability under ultrasound fields, which enables continuous diagnostic scanning with an excellent contrast effect. SONAZOID® was approved for market authorization in Japan, and ahead of other countries, in January 2007 for a focal liver lesion diagnosis indication.

A phase 3 confirmatory study in patients with focal breast lesions demonstrated a superiority of contrast-enhanced ultrasound with SONAZOID® compared to that of unenhanced ultrasound in accuracy of tumor characterization. Moreover, tolerability was also shown. SONAZOID® is expected to serve as a new option for the diagnosis of focal breast lesions and its disease management through its excellent diagnostic performance in differentiating benign and malignant lesions.

Outline of SONAZOID®

Product name	SONAZOID® 16μL vial for injection
Generic name	Perflubutane
Indications	For ultrasound imaging associated with the following: Focal liver lesions, <u>focal breast lesions</u> (underlined represents additional or modified indication)
Administration, dosage	Suspend 16μL (1 vial) of perflubutane microbubbles in the included 2mL injection solvent and administer the suspension intravenously. Usual dosage for an adult is 0.015mL/kg body weight in a single administration.
Licensor	GE Healthcare (Headquarter: UK)