

February 19, 2014

Dainippon Sumitomo Pharma Co., Ltd

Chelsea Therapeutics Obtains US FDA Accelerated Approval on
“NORTHERA™”

Osaka, Japan, February 19, 2014 — Dainippon Sumitomo Pharma Co., Ltd (Head Office: Osaka, Japan; President: Masayo Tada) (“DSP”) announced that Chelsea Therapeutics International, Ltd. (Head Office: North Carolina, U.S.A.) (“Chelsea”), DSP’s international licensee for droxidopa (generic name, brand name in Japan: DOPS[®]), a noradrenaline-induced adrenergic neurofunction improving agent, obtained the U.S. Food and Drug Administration (FDA) accelerated approval on the agent on February 18, 2014 (U.S. time) for the treatment of neurogenic orthostatic hypotension.

DSP granted to Chelsea in May 2006 exclusive rights and licenses to develop and commercialize the agent worldwide excluding Japan, Korea, China and Taiwan. Chelsea developed it in the U.S. for the treatment of neurogenic orthostatic hypotension and resubmitted an application for FDA approval in August 2013.

Chelsea plans to market the product under the brand name of “NORTHERA™” in the U.S. In addition, it has completed Phase II studies of the agent for fibromyalgia and for intradialytic hypotension.

<Reference>

An Overview of Chelsea Therapeutics International, Ltd.

Name: Chelsea Therapeutics International, Ltd.

Date of Establishment: 2004

Head Office: 3530 Toringdon Way, Suite 200 Charlotte, NC 28277

President and CEO: Joseph G. Oliveto

Businesses: Development and commercialization of innovative products for the treatment of a variety of human diseases that address important unmet medical needs or offer alternatives to current methods of treatment

About DOPS®

DOPS®, a precursor of noradrenaline (NA), is converted to NA thereby improving symptoms related to NA deficiency. DOPS® initially received approval in 1989 for the treatment of frozen gait and dizziness on standing associated with Parkinson's disease and others in Japan. In 2000, DSP received expanded marketing approval to include treatment of vertigo, dizziness and weakness associated with orthostatic hypotension in hemodialysis patients.

Contact:

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