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## NEWS RELEASE

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### FDA PROVIDES COMPLETE RESPONSE TO SEPRACOR'S NEW DRUG APPLICATION FOR STEDESA™

MARLBOROUGH, Mass., May 3, 2010 -- [Sepracor Inc.](#), a U.S. subsidiary of Dainippon Sumitomo Pharma Co., Ltd. (DSP), today announced that the U.S. Food and Drug Administration (FDA, or Agency) has issued a Complete Response Letter to Sepracor's New Drug Application (NDA) for its antiepileptic drug candidate, STEDESA™, which is the company's proposed trade name for eslicarbazepine acetate.

The FDA issued a Complete Response Letter to the STEDESA NDA indicating that its initial review of the NDA is complete but that the Agency will not approve the application at this time. Sepracor will meet with the FDA to discuss the Complete Response Letter.

“While we are disappointed by this decision, we are committed to working closely with the FDA to gain approval of STEDESA, which we continue to believe has significant potential to address the continuing unmet need in the treatment of patients with epilepsy,” said Saburo Hamanaka, Chairman and Chief Executive Office of Sepracor.

#### **About the STEDESA clinical development program**

STEDESA was studied in three Phase III, multi-center, randomized, placebo-controlled trials, which involved more than 1,000 patients from 23 countries. Patients involved in the trials had a history of at least four partial-onset seizures per month and no seizure-free period of more than 21 days despite treatment with one to three concomitant antiepileptic drugs. During the trials, patients were randomized to eslicarbazepine acetate or placebo, and after a 2-week titration period, were assessed over a 12-week maintenance period with continued follow-up over a one-year, open-label period.

BIAL-Portela & C<sup>a</sup>, S.A. (BIAL), a privately held, research-based Portuguese pharmaceutical company, was responsible for the research and development of eslicarbazepine acetate as adjunctive therapy in the treatment of partial-onset seizures in adults with epilepsy. Sepracor acquired the rights to further develop and commercialize eslicarbazepine acetate in the U.S. and Canadian markets from BIAL in late 2007.

#### **About Sepracor Inc.**

Sepracor Inc., an indirect, wholly owned subsidiary of Dainippon Sumitomo Pharma Co., Ltd., is a research-based pharmaceutical company dedicated to treating and preventing human disease by discovering, developing and commercializing innovative pharmaceutical products that are directed toward serving large and growing markets and unmet medical needs.

Sepracor's drug development program, together with its corporate development and licensing efforts, has yielded a portfolio of pharmaceutical products and candidates with a focus on respiratory and central

nervous system disorders. Currently marketed products include LUNESTA<sup>®</sup> brand eszopiclone, XOPENEX<sup>®</sup> brand levalbuterol HCl Inhalation Solution, XOPENEX HFA<sup>®</sup> brand levalbuterol tartrate Inhalation Aerosol, BROVANA<sup>®</sup> brand arformoterol tartrate Inhalation Solution, OMNARIS<sup>®</sup> brand ciclesonide Nasal Spray and ALVESCO<sup>®</sup> brand ciclesonide HFA Inhalation Aerosol. Sepracor's corporate headquarters are located in Marlborough, Massachusetts. For more information, please visit Sepracor's website at [www.sepracor.com](http://www.sepracor.com).

**About Dainippon Sumitomo Pharma Co., Ltd. (DSP)**

DSP is a multi-billion dollar, top-ten listed pharmaceutical company in Japan with a diverse portfolio of pharmaceutical, animal health and food and specialty products. DSP's strong research and development presence in the areas of CNS, diabetes, cardiovascular disease, and inflammation/allergy, is based on the merger in 2005 between Sumitomo Pharmaceuticals Co., Ltd., and Dainippon Pharmaceutical Co., Ltd. Today, DSP has more than 7,000 employees worldwide. Additional information about DSP is available through its corporate website at [www.ds-pharma.co.jp](http://www.ds-pharma.co.jp).

STEDESA is a trademark of BIAL-Portela & C<sup>a</sup>, S.A. LUNESTA, XOPENEX, XOPENEX HFA and BROVANA are registered trademarks of Sepracor Inc. OMNARIS and ALVESCO are registered trademarks of Nycomed GmbH.

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