

NEWS RELEASE

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FDA EXTENDS PDUFA ACTION DATE FOR STEDESA™ NEW DRUG APPLICATION

MARLBOROUGH, Mass., Jan. 27, 2010 -- [Sepracor Inc.](#) today announced that it has received notification from the U.S. Food and Drug Administration (FDA) that the agency now anticipates completing its review of the STEDESA™ (eslicarbazepine acetate) New Drug Application (NDA) on April 30, 2010, which is a three-month extension to the original Prescription Drug User Fee Act (PDUFA) date of January 30, 2010.

In November 2009, at the request of the FDA, Sepracor submitted additional information about STEDESA to the agency. This additional information was received by the FDA less than 90 days prior to the PDUFA action date of January 30, 2010. The FDA has authority to extend the PDUFA action date when additional data is provided by the NDA sponsor less than 90 days prior to the original PDUFA action date. This additional time is typically needed by the FDA to ensure that the agency has adequate time to review the additional information received.

About STEDESA

STEDESA, a new chemical entity, is a novel voltage-gated sodium channel blocker. STEDESA has been 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 despite treatment with one to three concomitant antiepileptic drugs. During the trials, patients were randomized to eslicarbazepine acetate or placebo, and after a two-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^a, S.A. (BIAL), a privately held Portuguese pharmaceutical company, was responsible for the research and development of eslicarbazepine acetate. Sepracor acquired the rights to commercialize eslicarbazepine acetate in the U.S. and Canadian markets from BIAL in late 2007.

Sepracor is seeking U.S. Food and Drug Administration (FDA) approval of STEDESA for adjunctive therapy with once-daily doses of 800 mg and 1200 mg in the treatment of partial-onset seizures in adults with epilepsy.

About Sepracor

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, have yielded a portfolio of pharmaceutical products and

candidates with a focus on respiratory and central nervous system disorders. Currently marketed products include LUNESTA[®] brand eszopiclone, XOPENEX[®] brand levalbuterol HCl Inhalation Solution, XOPENEX HFA[®] brand levalbuterol tartrate Inhalation Aerosol, BROVANA[®] brand arformoterol tartrate Inhalation Solution, OMNARIS[®] brand ciclesonide Nasal Spray and ALVESCO[®] 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.

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