

NEWS RELEASE

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SEPRACOR REPORTS PRELIMINARY RESULTS FROM A SECOND PHASE III STUDY FOR OMNARIS® HFA NASAL AEROSOL IN SEASONAL ALLERGIC RHINITIS

- In a large-scale Phase III study, OMNARIS HFA delivered in an aerosol nasal formulation propelled by HFA (hydrofluoroalkane), met its primary endpoint
- If Sepracor's development of OMNARIS HFA is successful and the FDA approves the product for use in the U.S., OMNARIS HFA would be one of the first nasal HFA formulations available for patients in the U.S. for the treatment of allergic rhinitis
- The U.S. market for nasal corticosteroids is estimated at approximately \$2.7 billion¹

MARLBOROUGH, Mass., June 30, 2010 -- Sepracor Inc. announced today the preliminary results of a large-scale, 671-patient Phase III study of OMNARIS® (ciclesonide) HFA, an aerosol nasal formulation of ciclesonide, for the treatment of seasonal allergic rhinitis (SAR) in adult and adolescent patients. In this study, OMNARIS HFA met its primary efficacy endpoint by demonstrating a statistically significant reduction versus placebo in the reflective total nasal symptom score averaged over a two-week treatment period. The total nasal symptom score, commonly referred to as TNSS, assesses the common allergy symptoms of nasal congestion, itching, sneezing, and runny nose and was recorded twice daily, once in the morning and once in the evening. In a previous Phase III SAR study of OMNARIS HFA, both ciclesonide doses (80 µg and 160 µg once daily) demonstrated clinically meaningful and statistically significant improvements in nasal symptoms compared with placebo.

"With the positive preliminary results obtained in this second Phase III clinical study, we continue to be encouraged by the potential benefits OMNARIS HFA offers those patients suffering from the effects of allergic rhinitis," said Saburo Hamanaka, Chairman and Chief Executive Officer of Sepracor. "We also believe the novel metered-dose device that we are developing to deliver this important treatment therapy is a truly differentiated, first-in-class delivery system that offers Sepracor an exciting opportunity to expand our leadership position within the respiratory marketplace."

One potential benefit of OMNARIS HFA and its differentiated delivery system is that the product may be able to reduce post-nasal drip and back-of-the-throat run-off that is commonly associated with currently available intranasal aqueous-based corticosteroids for the treatment of allergic rhinitis. The Allergies in America Survey, published in 2006, reports that approximately 33% of survey participants find "dripping down the throat" to be a moderately or extremely bothersome aspect of intranasal steroid products, and approximately 25% of survey participants have discontinued use of a nasal allergy prescription due to bothersome side effects. In contrast, the innovative nasal HFA device is designed to deliver a fine, dry mist of OMNARIS HFA medication to a patient's nose.

Ciclesonide is the active ingredient in OMNARIS HFA. Intranasal corticosteroids are well accepted as first-line therapy for the treatment of allergic rhinitis. OMNARIS HFA is being developed by Sepracor for commercialization in the U.S. under an exclusive distribution agreement with Nycomed.

“This is the second large-scale Phase III study Sepracor has completed and we are, once again, encouraged by the preliminary positive results we have received,” said Antony Loebel, M.D., Executive Vice President, Clinical Research and Medical Affairs at Sepracor. “OMNARIS in an HFA formulation has meaningful potential to provide physicians with a new method to treat patients suffering from nasal allergies. In addition to its efficacy, OMNARIS HFA offers the benefits of a unique delivery system that may help physicians improve patient comfort and compliance.”

About the Study

- 671 adult and adolescent patients at least 12 years of age with a history of SAR were randomized in a double-blind manner to receive ciclesonide HFA nasal aerosol 80 µg or 160 µg, or placebo once daily for up to two weeks.
- Efficacy was assessed by patient-reported average morning and evening reflective and instantaneous TNSS and total ocular symptom score (TOSS). TNSS assesses the common allergy symptoms of nasal congestion, itching, sneezing and runny nose. TOSS assesses ocular symptoms such as itching, tearing and redness of the eyes. The safety and tolerability of ciclesonide were also assessed in the trial.
- Both active treatments showed clinically meaningful and statistically significant differences in reflective TNSS compared with placebo over the two-week treatment period ($P < 0.0001$) thus meeting the primary endpoint of the study.
- Similarly, both active treatments also showed clinically meaningful and statistically significant differences in instantaneous TNSS compared with placebo over the two-week treatment period ($P = 0.0002$).
- Ciclesonide 80 µg demonstrated clinically meaningful and statistically significant improvements in ocular symptoms and RQLQ (Rhinconjunctivitis Quality of Life Questionnaire) vs. placebo ($P = 0.0124$). Ciclesonide 160 µg failed to demonstrate clinically meaningful and statistically significant improvements in ocular symptoms vs. placebo in this study.
- The drug was well tolerated, and the safety profile was similar across all of the treatment groups.

About Allergic Rhinitis

Allergic rhinitis, which is commonly referred to as hay fever, is a collection of symptoms, predominantly in the nose and eyes, to allergens such as dust, dander and pollen. The sensitized immune system produces antibodies to these allergens, which cause chemicals called histamines to be released into the bloodstream, causing itching, swelling of affected tissues, mucus production, hives, rashes and other symptoms. Symptoms vary in severity from person to person.²

Allergic rhinitis is estimated to affect approximately 60 million people in the United States. Specifically, it is estimated that between 10% and 30% of adults and as many as 40% of children are affected by the disease. Approximately 12 million physician office visits each year are attributed to allergic rhinitis.³

SAR, which is also often referred to as hay fever, is caused by an allergy to the pollen of trees, grasses, weeds or mold spores. Depending on the allergen, the season of the country and the pollination periods, SAR may occur in the spring, summer or fall and may last until the first frost.

Some people have symptoms of rhinitis no matter what the season. This is referred to as perennial allergic rhinitis, and it can be caused by allergens such as animal dander, indoor mold, dust mites and cockroaches.⁴

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[®] 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.

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.

¹Wolters Kluwer, moving annual total for nasal corticosteroids as of April 2010.

²MedlinePlus, a service of the U.S. National Library of Medicine and the National Institutes of Health. [Internet]. Available from: <http://www.nlm.nih.gov/medlineplus/ency/imagepages/19319.htm>. Accessed: June 14, 2010

³American Academy of Allergy, Asthma and Immunology (AAAAI). [Internet]. Available from <http://www.aaaai.org/media/statistics/allergy-statistics.asp>. Accessed: June 14, 2010

⁴American Academy of Allergy, Asthma and Immunology (AAAAI). [Internet]. Available from: <http://www.aaaai.org/patients/gallery/rhinitissinusitis.asp>. Accessed: June 14, 2010

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