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## **DAIICHI SANKYO, INC. ANNOUNCES FILING OF NEW DRUG APPLICATION FOR AMLODIPINE BESYLATE / OLMESARTAN MEDOXOMIL COMBINATION FOR THE TREATMENT OF HYPERTENSION**

Parsippany, NJ (November 28, 2006) – Daiichi Sankyo, Inc. announced today that it has filed a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) for a fixed dose combination of two antihypertensives, the calcium channel blocker (CCB) amlodipine besylate (currently marketed by Pfizer as Norvasc<sup>®</sup>) and the angiotensin receptor blocker (ARB) olmesartan medoxomil, or BENICAR<sup>®</sup>.

Pending approval, the combination will be indicated for the treatment of hypertension and may be used either alone or in combination with other antihypertensive agents. In a clinical trial, the amlodipine/olmesartan combination demonstrated clinically significant mean blood pressure reductions. It utilizes two complementary mechanisms of action, calcium channel blockade and angiotensin II receptor blockade. BENICAR, Daiichi Sankyo's currently marketed ARB, is the fastest growing medication in the fastest growing class of blood pressure-lowering drugs.<sup>1</sup> Norvasc<sup>®</sup> is the most widely used CCB on the market.<sup>2</sup>

"This therapy will further extend the range of hypertension treatments available, helping more patients reach their blood pressure goal," said Joseph P. Pieroni, President and CEO of Daiichi Sankyo, Inc. "Research and innovation in cardiovascular care is a therapeutic focus for Daiichi Sankyo, and this additional therapy is in line with our vision to contribute to the health and well-being of people worldwide."

More than 65 million Americans, or nearly one in three adults, are estimated to have high blood pressure.<sup>3,4</sup> Of those, roughly 30 percent are not aware that they have hypertension.<sup>5</sup> In those patients who are being treated for high blood pressure, about 66 percent are still not reaching a blood pressure goal of < 140/90 mmHg, a goal set by the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC-7), the body which creates clinical practice guidelines for managing high blood pressure in the U.S. According to JNC-7, most patients who are hypertensive will require two or more agents to reach blood pressure goals.<sup>6</sup>

"The majority of patients on blood pressure-lowering therapies do not reach their blood pressure goals," said Michael A. Weber, MD, Professor of Medicine and Associate Dean for Research, SUNY Downstate College of Medicine. "This unmet need demonstrates the importance of physicians prescribing the best possible treatment option to get more patients to blood pressure goals recommended by JNC-7 guidelines. Combining olmesartan and amlodipine, two well-known medications that have repeatedly demonstrated safety and efficacy in blood pressure lowering, provides patients and physicians

with a valid alternative to their current treatment options, which may lead to better patient compliance.”

### **About Daiichi Sankyo, Inc.**

Daiichi Sankyo, Inc. is the U.S. subsidiary of Japanese pharmaceutical company Daiichi Sankyo Co., Ltd. Headquartered in Parsippany, New Jersey, the company’s strategic focus is on cardiovascular diseases. Research and development of new therapies is also focused in the areas of glucose metabolic disorders, infectious diseases, cancer, immunology and bone and joint diseases. Daiichi Sankyo’s portfolio includes BENICAR<sup>®</sup> (olmesartan medoxomil) and BENICAR HCT<sup>®</sup> (olmesartan medoxomil/hydrochlorothiazide), the fastest growing angiotensin receptor blocker on the market, and WelChol<sup>®</sup> (colesevelam HCl), the number one branded bile acid sequestrant.<sup>7, 8</sup> For more information, please visit [www.daiichisankyo-us.com](http://www.daiichisankyo-us.com).

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\* mmHg = millimeters of mercury – units of blood pressure measurement

Norvasc<sup>®</sup> is a registered trademark of Pfizer Inc.

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<sup>1</sup> Data are representing May 2002 – February 2006 from IMS Health. National Prescription Audit, February 2006

<sup>2</sup> [www.norvasc.com](http://www.norvasc.com) – Last accessed October 12, 2006

<sup>3</sup> ibid

<sup>4</sup> The National Health and Nutrition Examination Survey (NHANES), 1999-2000

<sup>5</sup> The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC-7), <http://www.nhlbi.nih.gov/guidelines/hypertension/express.pdf>, Last accessed November 7, 2006.

<sup>6</sup> ibid

<sup>7</sup> Data are representing May 2002 – February 2006 from IMS Health. National Prescription Audit, February 2006

<sup>8</sup> IMS Health National Prescription Audit, September 2006