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## **Forest Laboratories and Adamas Pharmaceuticals Announce Forest's Submission of New Drug Application for Memantine Extended Release and Donepezil Fixed-Dose Combination for Alzheimer's Disease**

New York, NY and Emeryville, CA - March 04, 2014 - Forest Laboratories, Inc. (NYSE:FRX), a leading, fully integrated, specialty pharmaceutical company largely focused on the United States market, and Adamas Pharmaceuticals Inc., a privately held specialty pharmaceutical company, announced Forest's submission of a New Drug Application (NDA) to the Food and Drug Administration for a fixed-dose combination (FDC) of memantine HCl extended release (ER) and donepezil HCl for the treatment of moderate to severe dementia of the Alzheimer's type.

"The concurrent use of memantine and donepezil is a well-established treatment option for patients with moderate to severe dementia related to Alzheimer's disease. Using the two drugs together appears to provide benefit over using acetylcholinesterase inhibitors alone. Reducing the number of pills by offering patients a fixed-dose combination helps lessen the daily medication burden and could improve patient adherence and compliance," said Pierre Tariot, MD at the Banner Alzheimer's Institute, who has also consulted to both Adamas and Forest.

The memantine ER-donepezil HCl FDC, is a once-daily oral capsule for patients currently taking memantine (10 mg twice daily or 28 mg extended-release once-daily) and donepezil 10 mg. In addition, the capsules can be opened to allow the contents to be sprinkled on applesauce to facilitate dosing for patients who may have difficulty swallowing.

The New Drug Application consisted of two dosage strengths, 28mg/10mg (memantine extended release/donepezil) and 14mg/10mg (memantine extended release/donepezil) for patients with severe renal impairment. Memantine ER is the active ingredient in the currently marketed NAMENDA XR®, which is indicated for the treatment of moderate to severe dementia of the Alzheimer's type. Donepezil is the active ingredient in ARICEPT®, which is indicated for the treatment of mild to severe dementia of the Alzheimer's type. Forest and Adamas collaborated on the development of the fixed dose combination and Forest will have exclusive US commercialization rights while Adamas will retain exclusive commercialization rights outside of the US. The FDC product is covered by multiple Adamas patents and a Forest patent that extend to 2029.

### **About Alzheimer's disease**

Alzheimer's disease is a progressive, neurodegenerative disorder characterized by problems with memory, thinking and behavior that eventually become severe enough to affect daily tasks. An estimated 5.2 million people in the United States are currently living with Alzheimer's disease. Alzheimer's disease is the fifth leading cause of death in the United States among those aged 65 and older, and was reported as an underlying cause of death for more than 83,000 Americans in 2010.

### **About Adamas Pharmaceuticals, Inc.**

Adamas Pharmaceuticals is driven to improve the lives of those affected by chronic central nervous system (CNS) disorders by enhancing the pharmacokinetic profiles of approved drugs to create novel treatments for use alone and in fixed-dose combination products. The Company is currently advancing a pipeline of aminoadamantane-based drug candidates for the treatment of a complication of Parkinson's disease, chronic behavioral symptoms associated with traumatic brain injury and dementia associated with Alzheimer's disease. The Phase 2/3 EASED study investigating ADS-5102 (amantadine HCl ER) for the treatment of levodopa-induced dyskinesia in Parkinson's disease has been completed and met its primary endpoint. MDX-8704 (memantine HCl ER/donepezil) is a fixed-dose combination product candidate in late-stage investigation for the treatment of dementia associated with Alzheimer's disease. In November 2012, Adamas entered into an agreement with Forest Laboratories, Inc. for the development and commercialization of MDX-8704 in the United States. Adamas plans to advance its product candidates through approval and to commercialize approved products in the United States through a specialty CNS sales force. For more information about Adamas, please visit [www.adamaspharma.com](http://www.adamaspharma.com)

### **About Forest Laboratories and Its Products**

Forest Laboratories (NYSE: FRX) is a leading, fully integrated, specialty pharmaceutical company largely focused on the United States market. The Company markets a portfolio of branded drug products and develops new medicines to treat patients suffering from diseases principally in the following therapeutic areas: central nervous system, cardiovascular, gastrointestinal, respiratory, anti-infective, and cystic fibrosis. Our strategy of acquiring product rights for development and commercialization through licensing, collaborative partnerships, and targeted mergers and acquisitions allows us to take advantage of attractive late-stage development and commercial opportunities, thereby managing the risks inherent in drug development. The Company is headquartered in New York, NY. To learn more, visit [www.FRX.com](http://www.FRX.com).

Except for the historical information contained herein, this release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements involve a number of risks and uncertainties, including the difficulty of predicting FDA approvals, the acceptance and demand for new pharmaceutical products, the impact of competitive products and pricing, the timely development and launch of new products, and the risk factors listed from time to time in Forest Laboratories' Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and any subsequent SEC filings. Forest assumes no obligation to update forward-looking statements contained in this release to reflect new information or future events or developments.

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<b>For Forest Laboratories</b>	<b>For Adamas</b>
Frank J. Murdolo Vice President - Investor Relations 212-224-6714 media.relations@frx.com	Gregory T. Went Chief Executive Officer 510-450-3502 gwent@adamaspharma.com
Amanda Kaufman Media Relations amanda.kaufman@frx.com	