

# Lilly, Alcon Sign Marketing Agreement for Potential Diabetic Retinopathy Agent

Eli Lilly and Company (Indianapolis) and Alcon (Fort Worth, Texas) have signed a long-term agreement to copromote ruboxistaurin (proposed brand name Arxxant) in the United States and Puerto Rico. Ruboxistaurin is an investigational oral drug for the treatment of moderate-to-severe nonproliferative diabetic retinopathy. The copromotion agreement is subject to Food and Drug Administration approval of ruboxistaurin, which is currently being looked at by the agency under “priority review” status.

“We believe combining the respective expertise of

Lilly and Alcon will allow us to maximize the value of this potential new therapy for patients, physicians and our shareholders,” said Khoso Baluch, vice president, US diabetes business unit, for Lilly. “With this collaboration, we gain a highly reputable and experienced partner in the eye care market. Alcon will lead the promotional efforts to the eye care community, increasing awareness of the benefits that [ruboxistaurin] could provide if approved as the first oral medication to reduce the risk of vision loss associated with diabetic retinopathy.” For more information, please visit [www.lilly.com](http://www.lilly.com).

## Nastech Enters Into Development, License Agreement With Amylin

Nastech Pharmaceutical Company (Bothell, Wash) announced an agreement with Amylin Pharmaceuticals (San Diego) to develop a nasal spray formulation of exenatide (Byetta; Eli Lilly and Company and Amylin). Preclinical studies of the formulation have been completed in preparation for initiating studies to determine feasibility in human subjects, according to a company news release.

Under terms of the agreement, Nastech will receive milestone payments and royalties on product sales. If feasibility is successful and the program moves forward, milestone payments could reach up to \$89 million in total, based on specific development, regulatory and commercialization goals. Royalty rates escalate with product success. No other financial terms of the agreement were disclosed.

Amylin and Nastech will jointly develop the nasal spray formulation using Nastech’s proprietary nasal delivery technology, and Amylin will reimburse Nastech for any development activities performed by Nastech under the agreement. Amylin has overall responsibility for the development program including clinical, non-clinical and regulatory activities, while Nastech’s efforts will focus on drug delivery and chemistry, manufacturing and controls activities.

If a supply agreement is reached between the companies, Nastech may supply commercial product to Amylin and their exenatide partner, Lilly. For more information, please visit [www.nastech.com](http://www.nastech.com).

## Digital Healthcare Software Used in Pioneering Study of Blindness Treatment

A software system developed by Digital Healthcare, a Cambridge company that is the United Kingdom’s leading supplier of ophthalmology software, is being used in a pioneering study to monitor the impact of new health care treatments in ophthalmology.

According to a company news release, in a unique partnership with three image reading centers (Figure 1)



Figure 1. Alyson Muldrew, senior grader at the Belfast Angiographic Reading Centre, Queen’s University Belfast, uses Digital Healthcare’s Clinical Trials iP Software to assess a patient with AMD as part of a nationwide study to monitor the impact of photodynamic therapy with verteporfin involving 50 regional eye units and 12,000 patients over the next 4 years.

located in The Queen's University of Belfast, St. Paul's Eye Unit, Liverpool and Moorfields Eye Hospital, London, the company's Clinical Trials iP software will enable health care staff to analyze digital images of the retina gathered from some 3,000 patients per year over the next 4 years, in 50 regional eye units across the United Kingdom.

The results from this study will be used to measure the effectiveness of a specialist drug and verteporfin photodynamic therapy as a treatment for patients suffering from neovascular age-related macular degeneration (AMD). The study could also serve as a model for future programs to monitor health care treatments.

The Clinical Trials iP software is a sophisticated electronic platform that combines the capacity to handle the huge volumes of imaging data captured to diagnose and treat neovascular AMD, with an electronic patient care management system. After reading center staff have used the system to import thousands of retinal images, they can electronically transfer the data between a network of computers for grading using a secure telemessaging facility.

Professor Usha Chakravarthy of the Centre for Vision Science at Queen's University, Belfast and Ophthalmic Consultant at Belfast's Royal Hospitals, is one of the lead clinical investigators involved in delivering treatment for patients with neovascular AMD.

Professor Chakravarthy said, "This is a defining moment in the introduction of new technologies in that it will provide robust findings on the long-term benefits of verteporfin photodynamic therapy for the [neovascular] form of [AMD], which afflicts several thousand older adults annually."

So far, more than 5,000 images or angiograms from more than 3,000 patients have been submitted in digital and film formats from the 50 regional treatment centers to the Central Angiographic Resource Facility in Belfast and imported into Digital Healthcare's Clinical Trials iP software.

## GenoMed Can Explain Link Between West Nile, Diabetes/Hypertension

GenoMed (St. Louis, Mo) announced that it has already published why patients with diabetes and hypertension should be at increased risk of getting West Nile virus (WNV) encephalitis, according to a news release. This observation has now been made in

California, New York and Texas.

The link appears to be overactivity of the angiotensin-I converting enzyme (ACE). In 2002, GenoMed published a series of four articles showing that overactivity of ACE led to diabetes and hypertension, as well as to complications such as heart and kidney disease. Using the correct dose of the right ACE inhibitor, it was possible to reverse diabetic or hypertensive kidney disease for the first time, according to the company.

In 2004, GenoMed published that a similar approach was successful in treating more than 80% of patients with WNV encephalitis. GenoMed's treatment success rate for WNV encephalitis is currently 86% (19 of 22 patients improved rapidly).

In 2003, GenoMed filed patent applications claiming that ACE inhibitors and angiotensin II blockers may be a near-universal viral antidote, because previously healthy people who get sick from nearly all viral diseases suffer from a cytokine storm initiated by too much angiotensin II. GenoMed's viral antidote was included in the Project BioShield II Act of 2005, since it would be an ideal public health response to viral bioterrorism.

"GenoMed goes from the molecular mechanism of disease directly to practical treatments that are safe and useful at the population level. It's very gratifying to get separate epidemiologic confirmation that we've discovered something huge," said David W. Moskowitz, MD, GenoMed's CEO and chief medical officer. For more information, please visit [www.genomed.com](http://www.genomed.com).

## Minute Maid Orange Juice Now Available With Plant Sterols

Minute Maid orange juice (The Coca-Cola Company, Atlanta) with added plant sterols is clinically proven to help reduce cholesterol, according to company literature. The sterols are believed to work through the normal digestive process by blocking the absorption of cholesterol in the small intestine.

In a clinical study of men and women with normal to borderline high cholesterol, conducted at a major medical center, participants lowered their LDL cholesterol significantly by drinking two 8-oz servings of Minute Maid Premium Heart Wise orange juice daily with meals for 8 weeks. For more information, please visit [www.minutemaids.com/products/minute\\_maid\\_orange\\_juice/heart\\_wise.shtml](http://www.minutemaids.com/products/minute_maid_orange_juice/heart_wise.shtml). ■