FROST & SULLIVAN

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# Frost & Sullivan Recognizes Novagali Pharma for Innovation in Ophthalmic Therapies

## Improving the Administration, Bioavailability, Safety, and Efficacy of Treatments

MOUNTAIN VIEW, Calif. — 19th March 2009 — Based on its recent analysis of the ocular drug delivery market, Frost & Sullivan recognizes Novagali Pharma with the 2009 North American Frost & Sullivan Award for Industry Innovation & Advancement of the Year, for its two proprietary emulsion technology platforms, Novasorb and Eyeject.

It is estimated that as little as five percent of a topically applied drug ever reaches the intraocular tissues due to drug loss as the result of tearing, lacrimal fluid-eye barriers, and blood-ocular barriers. These beneficial natural defenses, which protect the eyes and block foreign substances, also greatly limit the usefulness of topical treatments for treating them when distressed or diseased. This is true, in particular, for diseases of the posterior of the eye.

“Novagali recognizes this as an opportunity and is working diligently with its proprietary emulsion technologies to overcome both pharmacological and drug delivery challenges in the eye,” says Frost & Sullivan Research Analyst Misty Hughes. “With research truly encompassing all segments of the eye, Novagali’s Novasorb is optimized to treat a number of diseases by improving drug delivery to the front of the eye, while the minimally-invasive Eyeject intra-ocular platform offers improvements over existing implant technology in treating challenging diseases of the eye’s posterior.”

Novasorb is a cationic emulsion technology platform being investigated to treat dry eye, glaucoma, allergies, and anterior uveitis. As the effective treatment of surface ocular conditions is often limited by dispersion and lubrication, Novasorb technology increases the absorption and efficacy of drugs in ocular tissues through electrostatic attraction between the positive charge of the therapeutic emulsion and the eye’s negatively charged mucous, cornea, and conjunctiva. Furthermore, the electrostatic attraction and colloidal properties that increase therapeutic residence time on the eye’s anterior, also benefit the eye’s posterior. Increased contact and penetration into the cornea and conjunctiva allows for more of the drug to diffuse to the anterior segment as well.

Compared to conventional eye drops and anionic emulsions, Novasorb formulations exhibit a four-fold higher spreading coefficient allowing for increased wettability of the eye’s surface while also protecting against mechanical damage that occurs from blinking. This increase in residence time on the surface of the eye is key to achieving therapeutic drug levels when treating ocular conditions. It also means the patient will require fewer instillations, which will undoubtedly decrease side effects and increase patient compliance.

Novagali has further expanded upon its novel emulsion technology platform to also treat serious diseases of the back of the eye. Eyeject is an intra-ocular delivery platform that offers a minimally-invasive alternative to ocular implants for treating disease in the eye’s posterior. This injectable emulsion provides a prolonged, controlled release of medication at the retina and choroid, yet can easily be administered in a non-surgical setting. Safe and effective, Eyeject is an organic, solvent- and preservative-free emulsion that includes only ophthalmologically biocompatible excipients. Novagali is investigating Eyeject’s use in treating a number of posterior ophthalmic diseases, including macular edema and diabetic retinopathy.

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Novagali's broad research portfolio includes seven compounds that utilize Novasorb or Eyeject technology to treat not only common eye conditions, but orphan diseases as well. Commercialized for sale in France in April 2008 and an expected U.S. launch, Cationorm®, an over-the-counter (OTC) dry eye treatment developed on the basis of Novasorb technology, is the company's first product from its pipeline to reach the market. The company's other lead drug candidates in development in the U.S. include Cyclokat (NOVA22007), a Novasorb-based therapy in phase III trials for moderate-to-severe dry eye, and Cortiject (NOVA63035), a corticosteroid formulated with Eyeject technology that is in phase I trials for diabetic macular edema.

"The development of new products that operate through novel mechanisms of action is vital to future advancements in ocular drug delivery," stresses Hughes. "Through focused research into novel treatment modalities in ophthalmics, Novagali Pharma's proprietary technology platforms are set to greatly benefit both patients and healthcare practitioners in the near future."

In recognition of Novagali's dedication and pioneering research in this field Frost & Sullivan is proud to present it with the 2009 North American Industry Innovation and Advancement of the Year Award in ocular drug delivery.

Each year, Frost & Sullivan presents this award to the company that has proven to be a leader in the industry and that, through its pioneering technology, sound business strategy, and research efforts, has been successful in moving the state of the industry forward. Its excellence in the field has extended beyond its technical advancements and encompasses a comprehensive view of market participants, resulting in an ongoing improvement in the industry, more comprehensive participation in the industry and for its contributions to the advancement of the market.

Frost & Sullivan's Best Practices Awards recognize companies in a variety of regional and global markets for demonstrating outstanding achievement and superior performance in areas such as leadership, technological innovation, customer service, and strategic product development. Industry analysts compare market participants and measure performance through in-depth interviews, analysis, and extensive secondary research in order to identify best practices in the industry.

**About Novagali Pharma**

Novagali Pharma is an ophthalmic pharmaceutical company that develops and commercializes innovative products. Thanks to its proprietary technology platforms Novasorb® and Eyeject®, the company has developed innovative products addressing main ocular conditions as well as orphan diseases. Most advanced products include Vekacia®, for treatment of vernal keratoconjunctivitis, Cyclokat®, for the treatment of moderate-to-severe dry eye syndrome and Cortiject® for the treatment of diabetic retinopathies. Cationorm®, indicated for dry eye symptoms is commercialized in France since April 2008. Founded in 2000, Novagali Pharma is based in the Génopôle biocluster in Evry (France).

**About Frost & Sullivan**

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