



NOVALAR announces exclusive license to develop and commercialize antibiotic fiber for root canal therapy

Addition of second product establishes solid dental pipeline for company

SAN DIEGO, July 25, 2007 – Novalar Pharmaceuticals, Inc. today announced it has entered into an exclusive, worldwide licensing agreement with The Forsyth Institute to develop and commercialize a product for the prevention of inter-appointment pain and bacterial reduction in endodontic treatment (root canal therapy). The product, an antibiotic-impregnated ethylene vinyl acetate (EVA) fiber, was originally developed by Forsyth Institute and Harvard School of Dental Medicine.

“This technology is an excellent strategic fit for Novalar,” said Donna Janson, President and Chief Executive Officer of Novalar. “A dental pharmaceutical pipeline will leverage the infrastructure we are putting in place to support the launch of our lead product, NV-101, a local anesthetic reversal agent.”

Under the terms of the agreement, Novalar will have an exclusive worldwide license for the technology from the Boston-based Forsyth Institute, an organization dedicated to scientific research and education in oral, craniofacial and related biomedical sciences. Novalar will be responsible for all development and commercialization costs and activities. In return, Forsyth will be entitled to milestone payments and royalties on products sold.

The elimination of bacteria from infected root canals is a cornerstone of endodontic therapy. Root canal treatment is required when the dental pulp, or nerve, becomes infected with bacteria, usually resulting from dental decay or trauma. During treatment, the infected root is removed, the canal is cleaned and refilled with sealer cement.

In this new therapeutic product, clindamycin would be incorporated into an EVA fiber and directly inserted into the root canal enabling a low dose, targeted, and local delivery of antibiotic. The fiber would be removed prior to filling the root canal.

Of the estimated 17 million root canal procedures done annually in the U.S., a significant number require multiple visits due to complex anatomy or acute infection. To treat infections during these procedures, an intra-canal treatment is often used. The most widely used intra-canal treatment today is calcium

hydroxide. High dose oral antibiotics, such as clindamycin, are prescribed as well but systemic treatment is generally reserved for more severe infections. Clindamycin is highly effective against gram negative organisms that commonly infect the root canal and are associated with symptoms such as pain and swelling.

“A local delivery system represents an opportunity to treat the infection effectively with a lower dose of medication—in this case clindamycin,” explains Dr. Bruce Rutherford, Novalar’s Vice President, Clinical Development.

Forsyth collected preliminary data on 57 endodontic patients and tested clindamycin-EVA, calcium hydroxide paste and an untreated control group. At the conclusion of the 1 week period, patients treated with clindamycin-EVA fiber had no clinical signs or symptoms of pain or hypersensitivity. Patients in the control groups demonstrated substantially more pain and swelling. In addition, preliminary market research conducted by Forsyth showed strong interest in the product concept by general dentists and endodontists.

“We are currently developing the timeline for submission of an Investigational New Drug (IND) application for this exciting new dental product,” Janson added. “With this agreement, Novalar has taken another key step in building its future.”

About Novalar Pharmaceuticals, Inc.

San Diego-based Novalar Pharmaceuticals, Inc. is a privately-held dental specialty pharmaceutical company dedicated to developing and commercializing novel oral healthcare solutions. The company’s initial product offering, NV-101, is being evaluated as a local anesthetic reversal agent and was developed to rapidly reverse the lingering and debilitating lip and tongue numbness associated with local dental anesthesia. For more information, visit www.novalarpharm.com.

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