

Methapharm Meets Success in the Asthma Market

By Jennifer L. Gillespie

When the Canadian Ministry of Health was searching the continent for a provider of Pharmaceutical-grade methacholine, they turned to ACIC Fine Chemicals, a global supplier to the pharmaceutical market with 30 years of expertise.

Research institutes began using the chemical as a tool for diagnosing bronchial inflammation and asthma and met with success. A few months later, a U.S. pharmaceutical company approached ACIC asking them to supply a pharmaceutical standard product.

"When we discovered there was a market for vials of methacholine, we created Methapharm," recalls Luciano Calenti, president and founder of Methapharm Inc., headquartered in Coral Springs, Fla. The company was formed in 1995 as part of CH¹ holdings, which includes ACIC Fine Chemicals.

Methapharm was licensed by Hoffman LaRoche, headquartered in Basel, Switzerland. It launched Provocholine[®] methacholine chloride USP powder for inhalation after receiving approval of its new manufacturing site from the U.S. Food and Drug Administration (FDA) in 1998 and Health Canada in 1999. The company also is in the process of registering pharmaceutical-grade methacholine in Europe.

The parasympathomimetic (cholinergic) bronchoconstrictor is to be administered in

solution only, by inhalation, for diagnostic purposes. It's indicated for diagnosing bronchial airway hyperactivity in patients who do not have clinically apparent asthma.

Methapharm has responded to increasing demand for their product by enhancing supply, distribution and customer-satisfaction processes. "We've developed a good rapport with our clients, and they trust that the product is continuously available," Calenti reports.

FUTURE PLANS

To further serve the asthma and allergy market, Methapharm looks to acquire other companies and product lines. Future plans include offering allergy testing equipment, dosimeters, nebulizers and inhalation products for the treatment of asthma.

"We have a mandate to build a full-fledged asthma and allergy pharmaceutical company," Calenti says.

Some diagnostic testing equipment was launched in September. The company has signed an agreement with a U.S.-based diagnostic equipment company for distribution of a spirometer in Canada and the United States. The Canadian operations are based in Brantford, Ontario.

Methapharm will offer free training in using the diagnostic test and help with selecting equipment. The company's respiratory therapist is available to provide in-service assistance and to answer any related questions. Customers also can receive a self-study module with an hour-long CD-ROM. This quality assurance (QA) program is a comprehensive resource and training manual for professionals wishing to start Provocholine challenge testing or may be implemented as a ready-to-use QA program for facilities currently performing Provocholine challenge tests.

"We feel that if the diagnostic test is done precisely and well, it will enhance the product," Calenti says.

EDUCATING CUSTOMERS

The recent tragedy at Johns Hopkins Bayview Medical Center, Baltimore, where a person participating in a clinical trial died during an asthma experiment, presented an important educational opportunity.

Although Provocholine from Methapharm was not used in that incident, questions from clients started pouring in. This prompted the company to send out an advisory explaining that the study involved a chemical-grade methacholine, not pharmaceutical-grade. They wanted to make sure clinicians understood the difference between the two and that the type of product used in a challenge test is critical, in addition to following protocols.

"People might think the whole methacholine test is suspect, but it isn't," Calenti says. "We've tried to educate without taking advantage of a very sad situation... and as a result of what happened, we have decided to conduct some more studies to enhance our product for future use."

For more information on Methapharm Inc., call (800) 287-7687 or see the company's Web site at www.methapharm.com. ■



Luciano Calenti, president and founder of Methapharm Inc.
photo/courtesy ACIC Chemicals Inc.

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