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Nanocrystalline drug moves into phase II trials for dermatitis indication

By Rosemary Clandos

Nucryst Pharmaceuticals Corp. has launched a phase II clinical trial for its nanocrystalline silver drug designed to treat inflammation and infection associated with an itchy form of eczema -- atopic dermatitis.

A subsidiary of Westaim Corp. (NASDAQ:WEDX; TSE:WED) Nucryst is winking at an \$800 million market for anti-inflammatory topical products that treat eczema, psoriasis, and acne if the trials prove the drug's safety and efficacy.

Although the study will answer questions related only to atopic dermatitis -- a condition that affects 20% of the general population -- the product formulation may also be helpful in the treatment of psoriasis. Additionally, the anti-microbial and anti-inflammatory properties of nanocrystalline silver could potentially be used to treat acne.

"Those are three big market areas for dermatology," Scott H. Gillis, president of the Wakefield, MA-based firm, tells *NanoBiotech News*. "The efficacy and safety profile of our drug will have a big impact on the portion of the market that we can capture."

The trial, which began in late November at 20 clinical sites in the U.S., involves 180 adults with mild to moderate forms of atopic dermatitis. "It's not limited to that population," says Gillis. "It is very possible that it could be used for more severe forms of eczema."

Silver has been used to treat infections for centuries. Some old medical literature states that a thin film of silver foil placed on wounds can reduce redness. For decades, silver nitrate solution and silver sulfadiazine cream has been used to treat burns and chronic wounds. But now, Nucryst has taken silver on a quantum leap into the nano realm.

Nucryst disassembles large crystals of pure silver and reassembles them in a novel nanocrystalline structure that quickly reacts when exposed to body fluids.

"It seems as if this novel form of nanosized silver supercharges its properties," says Gillis. "So it seems to kill bacteria more rapidly and reduce inflammation in a significant way, more than other forms of silver."

Nucryst's in vivo studies have shown that nanocrystalline silver kills microbes within one hour,

compared to 24 hours when other forms of silver are used. And it significantly reduces inflammation.

Gillis says researchers don't fully understand all of the healing mechanisms of silver, but in their animal studies, they have seen a dramatic reduction in inflammation in contact dermatitis in one or two days. Skin is nearly normal in five days.

Nucryst's nanocrystalline silver could offer patients an alternative to steroids, which may cause side effects such as skin atrophy or thinning, spider veins, and reduced effectiveness with long-term usage.

Since 1998, Nucryst has used its nanocrystalline silver technology in Acticoat, a microbial dressing for burns. In 2001, Nucryst entered a partnership agreement with London-based Smith & Nephew, which moved Nucryst's product from burn units and wound healing clinics in two countries to 27 countries. And product sales are increasing by 50% each year.

"For a small company, we think that partnering is very important," says Gillis.

"However, it's too early for us to have finalized any partnering decisions about our dermatology product."

Other indications in the works

In the meantime, Nucryst has considered ways to deliver nanocrystalline silver through inhalation to treat lung diseases and inflammation.

"Conceptually, we can go many places with this technology," says Gillis. "As a small company we need to focus our energy and we've chosen dermatology. It's a natural step from wound dressing."

"In the longer term, we'd like to look at gold and platinum and see if our nanocrystalline structures can enhance the properties of those metals. But I'm a big believer that you need success commercially and scientifically. Once we have success in the other areas, then there is clearly more research that we'd like to do," says Gillis.

Although Nucryst is ahead of its schedule for clinical trials, Gillis says that it will still take about four to seven years before the FDA could approve the eczema product on a traditional track.

Editor's Note: Contact Scott H. Gillis at (781) 224-1444. ©