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Safety data in hand, Biopharmx slides acne drug into larger study

By Marie Powers, News Editor

Acne isn't the world's sexiest indication, especially in the context of the hundreds of deadly diseases that ravage the human body. Still, it's the most prevalent skin condition in the U.S., estimated by the American Academy of Dermatology to affect some 50 million individuals, with severe forms covering large areas of the body and sometimes resulting in permanent scarring.

Treating acne also is something of a catch-22, as patients with the most resistant forms usually are prescribed oral antibiotics, which may make them more susceptible to multidrug-resistant bacterial infections.

Biopharmx Corp. is seeking to build a better mousetrap, and early findings suggest that BPX-01, its hydrophilic gel formulation of the antibacterial and anti-inflammatory drug, minocycline, may prove more effective to treat acne than other topical alternatives, without the systemic effects of an oral drug. BPX-01 is designed to penetrate the skin and deliver the active ingredient directly to the site of acne development in the pilosebaceous unit.

In June, the company released top-line safety data from its phase IIa study showing that BPX-01 caused no cutaneous toxicity or adverse effects and that no minocycline was detected in patient bloodstreams at any time point. The fuller dataset, reported Monday, showed that daily use of the candidate, in a 1 percent dosage strength, reduced facial *Propionibacterium acnes* (*P. acnes*) by 91 percent after four weeks compared to baseline, representing a statistically significant advantage over the study's control vehicle.

The findings suggested that BPX-01 can effectively reduce *P. acnes* at a lower dose than commonly used in oral minocycline.

The phase IIa data, along with a patient exit study showing 100 percent satisfaction with use of the candidate, will allow Biopharmx to make a "seamless transition" into a larger phase IIb study that will assess the traditional phase II endpoint of change in inflammatory lesion counts, according to Greg Kitchener, the company's chief financial officer.

Biopharmx opted to break the trial into two parts to gather safety and patient satisfaction data "before going into a full-blown phase II study," added Kin Chan, executive vice president of research and technology. "We didn't want to spend the time and resources on a dose-finding study only to realize that the candidate didn't work or was irritating to patients," Chan told *BioWorld Today*. "It was very important for us to get information on safety and patient satisfaction up front, through a one-month study, and the outcome appears to be really good."

'ISSUING A LARGE RAISE IS VERY DILUTIVE'

The randomized, double-blind phase IIb study is expected to enroll 225 patients with moderate to severe inflammatory acne across 15 U.S. centers, testing BPX-01 1 percent or 2 percent topical gel compared to vehicle. Biopharmx expects the 12-week study to be fully enrolled by mid-October, setting up a study completion date in late January and initial data by early in the second quarter of 2017, according to Kitchener.

The Menlo Park, Calif.-based company already envisions moving BPX-01 into a phase III study in the third quarter of next year, with completion toward the end of 2018. But Biopharmx is holding off on the trial design as it entertains discussions with potential partners that began as soon as the phase IIa safety data were disclosed.

"They all love the product," Kitchener told *BioWorld Today*. "They see the possibilities within the acne space, which is more than a $3 billion market in the U.S. alone."

Biopharmx hopes to conclude an out-licensing deal early next year, allowing a partner to have a major say in design of the phase III program.

"We're actively discussing what the terms of a licensing agreement for BPX-01 might look like," Kitchener said.

Provided the remainder of the development program is successful, the candidate is positioned for a quick trip to the U.S. market through the 505(b)(2) regulatory pathway.

Biopharmx has an earlier stage dermatology candidate, BPX-02, that is expected to move into preclinical studies next year. The target for the biologic agent has not been disclosed.

The company, which eventually hopes to grow into a specialty dermatology company with its own commercial products, also is advancing a molecular iodine product in over-the-counter and prescription (BPX-03) formulations to accompany its approved dietary supplement, branded Violet. The product is

designed to help alleviate common symptoms associated with premenstrual breast discomfort and fibrocystic breast disease. However, Biopharmx had revealed that it plans to out-license that product line to a women's health or consumer products company.

Biopharmx, which has 27 employees, uplisted last year to the NYSE MKT. On Monday, its shares (BPMX) opened sharply higher, losing some steam during the day but still finishing ahead at 90 cents, a gain of 12 cents, or 15.4 percent. (See *BioWorld Today*, June 26, 2015.)

In the past year, the company, which has a market cap of just $26.27 million, has completed a number of small transactions, including the sale last week of about 2.27 million shares priced at 65 cents apiece in a private placement that generated gross proceeds of $1.475 million along with subscription agreements for a secured convertible promissory note of $1 million and for an unsecured convertible promissory note of $500,000.

"We will continue to fundraise throughout the year, and we're evaluating the best way to do that," Kitchener said. "To be honest, part of [our limitation] is our stock price and our valuation, so that issuing a large raise is very dilutive to our current shareholders."

The company needs additional capital to fully fund the phase IIb, he added, but its bargaining chip is its belief that outcome of the trial will provide a major value inflection point.

"We think that BPX-01 is really special," Kitchener maintained. "We know minocycline works. We know we penetrate extremely well into the skin. And we know from our phase IIa that we got great *p. acnes* reduction. I think all of that bodes well for a successful IIb study." //