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NovaDigm Unveils Data with Dual Fungal/Bacterial Vaccine

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While multidrug-resistant superbugs like methicillin-resistant *Staphylococcus aureus* (MRSA) and NDM-1 always steal the spotlight at the annual Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC), one topic that tends to fly under the radar is antifungals.

Many folks associate fungi with relatively mild conditions like tinea pedis (athlete's foot) and onychomycosis (toenail fungus). Yet Timothy Cooke, CEO of NovaDigm Therapeutics Inc., noted that fungal infections are "far more fatal" than many bacterial infections in the hospital setting. "If you get invasive candidiasis in your bloodstream or organ involvement, the mortality rate is 40 percent," he told *BioWorld Today*.

Candida also is prevalent – it is the third most-common hospital infection behind *Staphylococcus aureus* and *Pseudomonas aeruginosa*, Cooke said. And to top it off, surface proteins found on *Candida* show a high degree of homology with proteins on the biggest, baddest bacterium of them all: *Staphylococcus aureus* itself.

The discovery of that homology – made by John Edwards Jr., and colleagues at the University of California, Los Angeles' David Geffen School of Medicine – prompted NovaDigm's founding in 2005. The Grand Forks, N.D.-based biotech aimed to create a vaccine that could prevent both *Candida* and *Staphylococcus aureus*.

The technology is "very plain vanilla," Cooke explained. The vaccine contains a single recombinant *Candida* surface protein, Als3. Cooke likened the approach to existing vaccines for hepatitis B or human papillomavirus.

Despite its simplicity, NovaDigm's vaccine – dubbed NDV-3 – attracted $18 million in funding from Domain Associates in 2008. Cooke said the biotech also received grants worth $5 million from the NIH and $12 million from the Department of Defense.

Preclinical data have shown NDV-3 confers a high survival rate following a challenge with highly virulent doses of certain *Candida* or *Staphylococcus aureus* strains.

The first clinical data were unveiled at ICAAC: In a double-blind, placebo-controlled Phase I trial, NDV-3 was well tolerated and induced rapid seroconversion and both T-cell and antibody responses.

Cooke noted that the rapidity of the seroconversion is key: 75 percent within 7 days and 100 percent within 14 days. That speed is critical because patients in intensive care often contract hospital-based infections within two weeks, so the vaccine can't take a month to start providing protection, he said.

Cooke also noted that NDV-3 is the first vaccine to demonstrate protective efficacy against both fungal and bacterial pathogens – an unusual feat because fungi and bacteria represent two different kingdoms.

As of now, there are plenty of prophylactic vaccines for both viruses and bacteria, but none for fungi. NovaDigm is not alone in trying, however. Pevion Biotech AG has completed a Phase I trial with PEV7, its *Candida* vaccine for vulvovaginal candidiasis. And some *Candida* treatments, like Astellas Pharma Inc.'s Mycamine (micafungin) – are used prophylactically.

"All the big pharma companies" are working on *Staphylococcus aureus* vaccines," Cooke said, "and some are working on vaccines for *Pseudomonas aeruginosa* as well. He said such vaccines could eventually be rolled into a combination product that would protect high-risk patients against several of the top hospital-acquired infections, much like children receive combination vaccines to prevent a wide array of illnesses. If such a future comes to pass, NDV-3's ability to prevent two bugs should give it a leg-up.

For now, however, NovaDigm is focusing on its second Phase I trial, slated to begin next month.

That study will look at dose schedules, intramuscular vs. intradermal administration, and both the inclusion and exclusion of an adjuvant. The study is expected to pave the way for a Phase II trial to begin in the second half of 2012.

NovaDigm also recently began fundraising. The company expects to raise a Series B round to support the Phase II trial. ■

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