S. aureus Vaccine Project Is in Limbo

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Although it was successful in one late-stage trial, Staphylococcus aureus, a vaccine in development to combat Staphylococcus aureus, failed to meet the primary end point in a second pivotal trial.

The vaccine’s development is now on hold, perhaps indefinitely, according to Thomas H. McLain, president and CEO of Rockville, Md.-based Nabi Bio-pharmaceuticals.

Staphylococcus aureus targets S. aureus types 5 and 8, eliciting antibodies to the bacteria’s polysaccharide capsule, Mr. McLain said in an interview. The initial market would be people having elective invasive procedures.

In a randomized, double-blind, placebo-controlled study of 3,600 hemodialysis patients, there was no reduction in the incidence of infection with S. aureus types 5 and 8 compared with placebo.

The company issued only a press release in November; full data will likely be released after several months of analysis, Mr. McLain said. Meanwhile, the company withdrew its application for European Union approval and halted all development.

In their Phase III study, Staphylococcus aureus Induced partial immunity for 40 weeks in an end-stage renal disease population (N. Engl. J. Med. 2002;346:491-6). Results also seemed to be promising in a recently completed substudy, according to its principal investigator, Dr. Todd K. Rosengart head of cardiothoracic surgery at Stony Brook University Hospital, N.Y. In that study, conducted when Dr. Rosengart was at Evanston Northwestern Healthcare, Ill., 120 patients undergoing elective, open cardiac surgery were given either the vaccine or a sham injection.

A vaccine is definitely needed, but the bar for vaccine acceptance will be high, given the success of other S. aureus elimination techniques.

Cephalosporins Superior For Treating Group A Strep

Washington — Oral cephalosporins, whether given for 5 or 10 days, are more effective than penicillin in the treatment of Group A streptococcal tonsillopharyngitis, Dr. Janet R. Casey and Dr. Michael E. Pichichero reported in a poster at the annual Interscience Conference on Antimicrobial Agents and Chemotherapy.

Data were derived from a meta-analysis involving a total of 11,426 patients from 47 trials in the United States and Europe, said Dr. Casey and Dr. Pichichero, both of the Emlywood Pediatric Group and the University of Rochester, N.Y.

Among 10 European studies comparing 10 days of penicillin versus 10 days of cephalosporins in the bacterial eradication of GAS in a total of 1,656 pediatric patients with tonsilopharyngitis, the odds ratio was 4.27 in favor of cephalosporins. In 25 such U.S. trials, involving 5,469 patients, cephalosporins didn’t fare quite as well, although they were still superior to penicillin, with an odds ratio of 2.79.

Clinical cures for 10-day regimens were similar for the two continents, with odds ratios of 2.38 in Europe (7 trials/1,488 children) and 2.46 in the United States (22 trials/4,990 children). Studies of 4-5 days of cephalosporins versus 10 days of penicillin were analyzed in a total of 6 European and U.S. trials involving 1,149 adults and in 6 trials from both continents involving 3,112 children.

Odds ratios for bacterial eradication favored the shorter cephalosporin regimen for the 9 combined European trials (1.36) and even more so in the 3 U.S. trials (2.41). On both continents, the superiority of cephalosporins in bacterial eradication was more pronounced in children than in adults (odds ratios 1.34 vs. 1.09 in Europe and 2.94 vs. 1.65 in the United States).

Bacterial cure rates with cephalosporins were strictly superior to penicillin in trials from the United Kingdom, Germany, France, and Sweden, with odds ratios ranging from 3.35 to 4.77. While cephalosporin cure rates remained consistent in the different countries, penicillin bactericidal cure rates varied widely, by a low of 66% in Sweden. That’s probably because 2 of the 3 trials conducted there were among patients with recurrent GAS tonsillopharyngitis, in whom penicillin would be expected to be even less effective, Dr. Casey and Dr. Pichichero said at the meeting, sponsored by the American Society for Microbiology.

—Miriam E. Tucker