

The Anti-Infective Drugs Advisory Committee of the US Food and Drug Administration (FDA) has heartily endorsed ceftaroline (Cerexa Inc) for the treatment of community-acquired bacterial pneumonia (CABP) and complicated skin and skin structure infections (cSSSI).

At yesterday's meeting, in the morning session, the committee voted 21 to 0 in favor of ceftaroline for CABP, and in the afternoon, a slightly smaller committee voted 18 to 0 in favor of its use for cSSSI. There were no abstentions.

The committee was warm in its praise of the sponsor and the data it presented for both indications.

Ceftaroline is a beta-lactam of the cephalosporin class of antimicrobials with activity against aerobic and anaerobic gram-positive and aerobic gram-negative bacteria associated with skin and respiratory infections. It also has activity against methicillin-resistant *Staphylococcus aureus* and *Streptococcus pneumoniae*.

Members of the committee said they found it very easy to cast their affirmative votes when asked whether the sponsor had demonstrated safety and efficacy in CABP and cSSSI.

CABP Indication

"I thought this was a relatively easy decision to make," commented Dean Follmann, MD, from the National Institute of Allergy and Infectious Diseases of the National Institutes of Health, Bethesda, Maryland, in explaining his yes vote for the CABP indication.

"It was a very easy decision to make. The noninferiority margin was preserved in instances. In fact, it seemed that ceftaroline was strong enough to perhaps star in its own Old Spice commercial," said committee chair Thomas Moore, MD, from Ochsner Health System, New Orleans, Louisiana.

Erica Brittain, PhD, from the National Institute of Allergy and Infectious Diseases of the National Institutes of Health, said she wished all noninferiority trials were this easy to interpret, adding that she was "very impressed that there were hints of superiority all over the place" for ceftaroline.

John E. Bennett, MD, also from the National Institutes of Health, congratulated the manufacturer for a "well-designed, carefully conducted and conservatively analyzed study" and said he was impressed by the quality of the data.

However, he voiced one concern about the generalizability of the data supporting the CABP indication, which were collected in an eastern European population, to patients in the United States. "This population seems to be less sick than patients in this country, but apparently it's impossible to conduct these kinds of studies in the United States. I believe they tried, but I'm not completely assured that we could extrapolate those results to our patients."

One of the pediatricians on the panel, Sheldon L. Kaplan, MD, from Baylor College of Medicine and Texas Children's Hospital, Houston, said he was looking forward to the pediatric studies that the sponsor had promised. "I think this is a potentially fabulous drug for pediatric patients · one that will be very helpful to us · and I hope that we will have much more information on penetration into the [cerebrospinal fluid] because that is always a concern in patients who have pneumococcal bacteremia in particular."

cSSSI Indication

The committee was equally positive about ceftaroline for cSSSI, although some members voiced minor concerns.

Peter Katona, MD, from the David Geffen School of Medicine at the University of California. Los Angeles, said, "I have to admit, I have a weak spot for anything that could replace 2 drugs with 1 drug, which I hope is something that this drug could eventually do."

"I'm impressed at how difficult it is to get a homogeneous group of patients with skin and soft tissue [infections] together," commented Kent A. Sepkowitz, MD, from Memorial Sloan-Kettering Cancer Center, New York City. "The sponsor did a decent job."

Dr. Moore said that cefteteroline is now the poster child of how to get through the new FDA endpoints. He also thanked the FDA for their hard work "in crunching the data," adding that this emphasized the effectiveness of the drug.