SPEAKER: So while historically we've had the option for IV amikacin as a management tool for more advanced or refractory disease, the evolution in drug development has provided us an added agent and option. And that is the amikacin preparation that last fall was approved by the FDA for administration in a mycobacterium avium complex-infected patients with refractory disease. And they defined refractory disease as patients on therapy for at least six months who had persistent positive cultures through a set-- that six month period of active antibiotic therapy with standard, goal-based therapy strategies of multidrugs.

So what we now have available is this FDA-approved product of liposomal formulation amikacin for inhaled therapy and that that preparation is used as a single, once-a-day, inhaled dose and is formulated specifically for inhalation. And the liposomal formulation appears to have achieved a couple of interesting added biologic features, one of which is that available pharmacokinetics point out that that drug presence in the lung persists longer with the liposomal than for the pharmacokinetics seen with the unaltered amikacin itself so that pharmacokinetics appear to be extended in the lung-- that the second feature is that the liposomal formulation appears to be more avidly taken up into macrophages, which is an important biologic feature.

Because again, to remind us, these microbacteria exist substantively as intracellular organisms and specifically are in macrophage and monocyte populations so that if one can achieve a greater macrophage intracellular antibiotic concentration, that could potentially accord to a more potent biologic effect of that antibiotic on those intracellular pathogens-- so that in this liposomal construct, we then have extended pharmacokinetics of drug persistence in the lung plus a higher level of penetration of that same drug into these macrophages that hopefully would result in better killing and clearance of the infection in lungs.