Joint Efforts Led to Avastin Compromise

BY LEAH D. FARR, NEWS AND INDUSTRY EDITOR

After several months of uncertainty, retina physicians have been promised continued access to Avastin for off-label use, through a compromise developed by the three major stakeholders.

In a joint statement issued by Genentech, the American Academy of Ophthalmology (AAO), and the American Society of Retina Specialists (ASRS), physicians were informed that they could continue to prescribe Avastin (bevacizumab; Genentech, Inc., South San Francisco, California) and purchase it directly through authorized wholesale distributors. Wholesalers can then ship it to hospital pharmacies, compounding pharmacies, or directly to physician's offices.

In a member communication, the AAO called the new protocol a significant step forward. "We are delighted that what for a while looked like it might become a major interruption of the drug supply has been averted," AAO President David W. Parke, MD, told *Retina Today* in a telephone interview. "There may be a few individuals who need to develop special solutions to maintain access to Avastin, and we will not know that for a few months. Still, I have great confidence in the physicians' ability to be flexible and develop strategies."

WHAT STARTED IT

Genentech first drew fire from the retinal community and a US senator after an announcement in October 2007 that it would limit distribution of Avastin—an agent used off-label by ophthalmologists for the treatment of neovascular age-related macular degeneration (AMD) and other ocular conditions. Avastin is US Food and Drug Administration (FDA) approved as an oncology medication but has been widely used as a low-cost alternative to Genentech's drug, Lucentis (ranibizumab)—which is FDA approved for the treatment of neovascular AMD.

Senator Herb Kohl, chairman of the Special Committee on Aging, reported that the use of Lucentis instead of Avastin could cost Medicare $1 to $3 billion a year. The company is now working closely with Senator Kohl and committee staff to address their questions about the upcoming changes, Genentech spokeswoman Krysta Pellegrino told *Retina Today*.

Additionally, Genentech maintained its position on the value of Lucentis as the most appropriate treatment for AMD patients because the drug was "specifically designed, formally studied, FDA approved, and manufactured for intraocular delivery."

Genentech originally embargoed Avastin for ophthalmic use because of concerns raised by the FDA about the safety of repackaging it into smaller units. The new protocol gives doctors access, while enabling the company to stop selling the drug to compounding pharmacies.

Most surgeons should easily navigate this new process, Dr. Parke said. "A majority of the retinal community has some familiarity with the acquisition process. On the other hand, things are going to change and there may be some new wrinkles. Both the AAO and ASRS are going to have resources available to educate those members who have special circumstances or questions."

Genentech's statement also reassured physicians that it is not in the company's practice to interfere with prescribing practices. "Physicians should be able to prescribe the treatment that they believe is most appropriate for their patients," the company said.

OTHER CHANGES

Additionally, Genentech is working with the AAO and ASRS to improve its access and reimbursement programs for Lucentis. During the past several months, complaints that the existing Lucentis access program for low-income patients was cumbersome and incomplete have also surfaced.

"Genentech is committed to ensuring that no patient goes without treatment due to financial barriers alone and believes it is important for physicians to be aware of and utilize our access programs when needed," Ms. Pellegrino said.

The company is using the recent feedback to develop additional programs that efficiently facilitate patient access and expedite reimbursement for physicians. Updates on this progress will be provided in early 2008, according to the company. ■

For questions about Genentech's authorized wholesale distributors, contact +1 800 551 2231; or csordermgmnt-d @gene.com. For information regarding Lucentis access and reimbursement, contact Genentech's Lucentis Commitment helpline at +1 866 724 9394.