Pipeline, Partnerships, and Presentations: Genentech Commits to Ophthalmology

BY JENNIFER KREATSOULAS, NEWS & CONTRIBUTING EDITOR

Genentech Inc. (South San Francisco, CA) has been a leader in the biotech space for the past 3 decades, using human genetic information to discover, develop, manufacture, and commercialize biotherapeutic treatments for serious or life-threatening medical conditions.

In the retina community, Genentech is primarily known as the developer of two drugs that have revolutionized the management of age-related macular degeneration (AMD): ranibizumab, approved by the US Food and Drug Administration in 2006 for treatment of choroidal neovascularization (CNV) in AMD, and bevacizumab (Avastin), FDA-approved as a cancer therapy but widely used off-label as an intravitreal injection for the same purpose.

The rapid acceptance of ranibizumab has prompted Genentech to explore the drug's potential to treat other diseases of the eye, including diabetic macular edema (DME) and retinal vein occlusion (RVO). To this end, Genentech has expanded its involvement with the retina community to demonstrate its commitment to ophthalmic drug discovery and development.

OPHTHALMIC R&D

Retina Today recently spoke with John Snisarenko, Genentech's Vice President of Sales and Marketing for Lucentis, about the company's research and initiatives with the retina community. Mr. Snisarenko joined Genentech in December 2007 after heading up Novartis Ophthalmics in Canada for 14 years. He currently oversees approximately 80 employees who develop patient education, promotions, and marketing strategies for Lucentis (ranibizumab) and will do the same for other ophthalmic-related molecules that enter the pipeline.

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"We are continually hiring ophthalmic researchers to gain the expertise we need to grow our pipeline and our basic research teams," Mr. Snisarenko said.

PARTNERING WITH THE RETINA COMMUNITY

In addition to boosting ophthalmic research, Genentech has steadily been building long-term partnerships with organizations in the retina community, Mr. Snisarenko said. Genentech has worked closely with the American Society of Retina Specialists to share information, gather feedback, and discuss how the two organizations can work together to help patients, he said. One initiative that has come from this partnership is a joint Genentech-ASRS AMD awareness campaign designed to educate the public and those at risk about signs and symptoms and the importance of routine retinal exams.

"So often patients seek out retina physicians when they have lost vision that can't be redeemed," Mr. Snisarenko told *Retina Today*. "Our goal is to educate patients and create a general awareness about retinal diseases like AMD so that they visit their doctor long before permanent damage has been done."

The campaign primarily targets the older generation through publications such as *AARP The Magazine* and the *Reader's Digest Large Print Edition*. Mr. Snisarenko said Genentech and ASRS hope to expand the distribution to wider audiences in the future. The AMD awareness campaign, branded with the ASRS/Genentech logos, will also be promoted in doctors' offices, he said.

PATIENT FOCUS

With guidance from the American Academy of Ophthalmology and ASRS, Genentech recently enhanced its patient assistance program, Lucentis Access Solutions, based on input from patients, physicians, and advocates, to help improve enrollment, timing, and eligibility requirements. The financial criteria were modified to include household incomes of up to $100,000. Also, Genentech streamlined the turnaround time for approval from days to within 24 to 48 hours.

Mr. Snisarenko stressed that the goal of these enhancements is to guarantee that patients are not denied access to Lucentis because of financial constraints.

"We are trying to make sure that we can offer help from that perspective and remove that barrier so that patients who need access can get access," he said.

Lucentis Access Solutions is just one of the programs established since the 1980s under Genentech's Access To Care Foundation. Since 1985, Genentech has donated approximately $1 billion in free medicine to uninsured patients, according to the company. Since 2005, the Genentech Access to Care Foundation has provided free medicine to approximately 46,000 patients and has donated more than $140 million to independent nonprofit organizations that provide copay assistance.

FURTHER INNOVATIONS

Lucentis for AMD is not Genentech's only focus in ophthalmology, Mr. Snisarenko said. The company is exploring different dosing strategies and whether Lucentis can be used to treat other diseases of the eye.

Genentech is currently investigating the safety and efficacy of Lucentis for treatment of DME and RVO in four phase 3 clinical trials. Another trial is investigating genetic markers for AMD, and the company is interested in pursuing sustained delivery of Lucentis.

Furthermore, Genentech has acquired Tanox, Inc. (Houston, TX), which was in the early stages of testing an anti-factor D molecule as a potential treatment for dry AMD. The company plans to continue this testing in its own laboratories. Genentech is also committed to further study of its approved medicines to verify long term safety and efficacy, Mr. Snisarenko said. Six-month data from HORIZON, a phase 3b extension study that includes patients who have been receiving Lucentis for more than 3 years, will be presented at the Retina Society meeting. Final efficacy results from cohort 1 of the phase 3b SAILOR study, the largest study ever conducted in patients with wet AMD, were recently presented at Bascom Palmer Eye Institute's Angiogenesis, Exudation, and Degeneration 2008 meeting, and additional data will be available later this year.

The DAWN trial, to be presented at the American Academy of Ophthalmology meeting in November, is examining genetic variants for links to disease severity and CNV phenotype in Lucentis patients involved in the company's pivotal trials in wet AMD trials (MARINA and ANCHOR) and the role of genotype in best corrected visual acuity response to Lucentis treatment for wet AMD.

"The key message we want to convey with our pipeline, partnerships, and presentations this year is that we are committed to ophthalmology, retina specialists, and patients for the long run," Mr. Snisarenko told Retina Today. "Until there is a cure for AMD and other diseases like DME and RVO, we want to continue to develop innovative new medicines for patients." ■

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