### Ranibizumab Improves Acuity in Macular Edema

BY MIRIAM E. TUCKER

VIENNA — Ranibizumab treatment was associated with continuous improvement in best-corrected visual acuity and central retinal thickness over 12 months in a randomized, placebo-controlled study of 151 patients with diabetic macular edema.

The multicenter RESOLVE (Safety and Efficacy of Ranibizumab in Diabetic Macular Edema With Center Involvement) study randomized 51 patients to 6 mg/mL and 51 patients to 10 mg/mL of ranibizumab per intravitreal injection, and 49 patients to sham injections, Dr. Katrin Engelmann said at the annual meeting of the European Association for the Study of Diabetes.

Patients were given three initial monthly injections followed by retreatment based on predefined success or safety criteria. After the first month, the injection volume was doubled if central retinal thickness was greater than 300 mcm or was greater than 225 mcm and the reduction in edema from the previous treatment was less than 50 mcm. Best-corrected visual acuity (BCVA) and optical coherence tomography (OCT) were assessed monthly.

Injection volume was doubled in 65% of the ranibizumab patients (both dose groups combined), compared with 92% of the sham injection group. Rescue laser photocoagulation treatment was required in 9% of the ranibizumab group, compared with 33% of the sham treatment group.

The proportion of patients who gained visual acuity from baseline to month 12 was 90% with ranibizumab, compared

### EDITORIAL ADVISORY BOARD

**PAUL S. JELLINGER, M.D.,** University of Miami

Medical Editor in Chief

DONALD A. BERGMAN, M.D., Mount Sinai School of Medicine, New York LOUIS B. CHAYKIN, M.D., Nova Southeastern University, Davie, Fla. RHODA H. COBIN, M.D., Mount Sinai School of Medicine, New York A. JAY COHEN, M.D., University of Tennessee, Memphis

DANIEL S. DUICK, M.D., Endocrinology Associates, Phoenix, Ariz.

**Hossein Gharib, M.D.,** Mayo Clinic, Rochester, Minn.

YEHUDA HANDELSMAN, M.D., Metabolic Institute of America, Tarzana, Calif. RICHARD HELLMAN, M.D., University of Missouri, Kansas City

**DAVIDA F. KRUGER, M.S.N.,** Henry Ford Hospital, Detroit, Mich.

**PHILIP LEVY, M.D.,** University of Arizona, Phoenix

STEVEN M. PETAK, M.D., University of Texas at Houston

HERBERT I. RETTINGER, M.D., University of California, Irvine

HELENA W. RODBARD, M.D., Endocrine and Metabolic Consultants, Rockville, Md. DONALD A. SMITH, M.D., Mount Sinai School of Medicine, New York with 55% who received sham injections.

The mean BCVA increased and mean OCT decreased continuously over time in the ranibizumab patients. From baseline to month 12 there was a mean gain of 11.8 letters in the 6-mg/mL ranibizumab group, and 8.8 letters with the 10-mg/mL group (a pooled mean gain of 10.3 letters), compared with a loss of 1.4 letters in the sham treatment group, said Dr. Engelmann, of Klinikum

Chemnitz GmbH, Saxony, Germany.

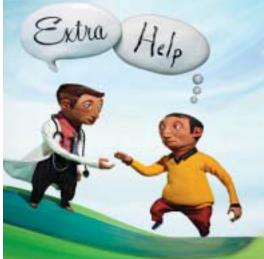
The most frequent ocular adverse events were conjunctival hemorrhage (14% sham, 23% ranibizumab) and eye pain (20% and 18%). Serious ocular adverse events occurred in one sham patient and in four ranibizumab patients. Nonocular arterial thromboembolic events occurred in two sham and three ranibizumab (10 mg/mL) patients.

Overall, the profile of ranibizumab in

diabetic macular edema as seen in this study was similar to that found in previous randomized controlled studies trials of patients with neovascular age-related macular degeneration, she noted.

Ranibizumab (Lucentis) is marketed in Europe by Novartis and in the United States by Genentech for the treatment of patients with wet age-related macular degeneration. Novartis funded the RE-SOLVE study.

## For your adult patients with type 2 diabetes struggling to gain glycemic control



# Onglyza (saxagliptin) 5 mg tablets

Significant reductions in A1C when partnered with key oral antidiabetic agents\*

- Onglyza is weight neutral
- Discontinuation of therapy due to adverse events occurred in 3.3% and 1.8% of patients receiving Onglyza and placebo, respectively
- Convenient, once-daily dosing
- Rapidly growing formulary access<sup>1</sup>

#### Indication and Important Limitations of Use

ONGLYZA is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

ONGLYZA should not be used for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis.

ONGLYZA has not been studied in combination with insulin.

### **Important Safety Information**

- Use with Medications Known to Cause Hypoglycemia: Insulin secretagogues, such as sulfonylureas, cause hypoglycemia. Therefore, a lower dose of the insulin secretagogue may be required to reduce the risk of hypoglycemia when used in combination with ONGLYZA
- Macrovascular Outcomes: There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with ONGLYZA or any other antidiabetic drug

Most common adverse reactions (regardless of investigator assessment of causality) reported in ≥5% of patients treated with ONGLYZA and more commonly than in patients treated with control were upper respiratory tract infection (7.7%, 7.6%), headache (7.5%, 5.2%), nasopharyngitis (6.9%, 4.0%) and urinary tract infection (6.8%, 6.1%). When used as add-on combination therapy with a thiazolidinedione, the incidence of peripheral edema for ONGLYZA 2.5 mg, 5 mg, and placebo was 3.1%, 8.1% and 4.3%, respectively.

\*metformin, glyburide, or thiazolidinedione (pioglitazone or rosiglitazone)

### Onglyza – A Welcome Partner

Please read the adjacent Brief Summary of the Product Information.
For more information about Onglyza, a DPP-4 inhibitor, visit www.onglyza.com.

Reference:
1. Fingertip Formulary® data as of October 2, 2009. Data on File, October 2009.



©2009 Bristol-Myers Squibb 422US09AB12901 10/09 Onglyza™ is a trademark of Bristol-Myers Squibb

