

Metastatic Breast Cancer Patients Rarely in Trials

VITALS

Major Finding: Fewer than 20% of women with metastatic breast cancer have ever participated in a clinical trial; the most common reason for this was the lack of encouragement to do so from a primary care physician.

Data Source: A survey of 1,342 women with metastatic breast cancer in 13 countries on five continents.

Disclosures: The investigator serves as a consultant to Pfizer Inc., which also funded the survey.

BY BRUCE JANCIN

SAN ANTONIO — Fewer than one in five women with metastatic breast cancer have ever participated in a clinical trial, according to a large international survey.

The No. 1 reason these women with incurable cancer cited for not participating in clinical trials that aimed at finding sorely needed

new treatments was that their primary physician hadn't recommended it, Catherine Glennon, R.N., reported at the San Antonio Breast Cancer Symposium.

Conversely, among the 18% of surveyed metastatic breast cancer patients who have participated in a clinical trial, nearly three-quarters cited encouragement from their primary health care provider

as their chief reason for enrolling, added Ms. Glennon, director of nursing outpatient cancer services at the University of Kansas Hospital in Kansas City.

She presented highlights of BRIDGE (Bridging Gaps, Expanding Outreach—Metastatic Breast Cancer Patient Survey). The survey, conducted by Harris Interactive, included 1,342 women with

Genetic Assay Often Alters Cancer Treatment

SAN ANTONIO — Treatment plans for women with estrogen receptor-positive early-stage breast cancer were significantly altered in up to 40% of cases in response to the additional information provided by Oncotype DX 21-gene recurrence score assay results, according to two physician surveys presented at the San Antonio Breast Cancer Symposium.

The general trend was for the Oncotype DX results to revise planned adjuvant treatment downward toward a less aggressive approach.

One survey involved 160 medical oncologists faced with patients with ER-positive breast cancer with 1-3 positive axillary lymph nodes. In the 138 cases where the physician had a specific treatment recommendation before receiving the Oncotype DX results, the recommended regimen was changed from chemotherapy plus hormone therapy to hormone therapy alone in 46 patients (33%) based on the additional information provided by the recurrence score assay, reported Dr. Ruth Oratz of New York University's School of Medicine.

Dr. Oratz said that she is on the speakers bureau for Genomic Health, which markets the Oncotype DX assay.

In addition, 13 patients (9%) were switched from planned hormone therapy to chemotherapy plus hormone therapy in response to the Oncotype DX data.

Fifty-three percent of patients in this series had a low Oncotype DX recurrence score below 18, another 38% had an intermediate score, and 9% had a recurrence score of 31 or more.

A separate survey presented in San Antonio involved the medical oncologists, surgeons, and pathologists for 154 consecutive women with early-stage, ER-positive breast cancer that was node negative in 130 cases.

Based on the standard clinicopathologic features alone, the physicians overestimated the patients' recurrence risk in 32% of cases and underestimated it in 14%, according to Dr. Geza Acs of H. Lee Moffitt Cancer Center & Research Institute, Tampa.

Dr. Acs, like Dr. Oratz, is on the speakers bureau for Genomic Health, which markets Oncotype DX.

—Bruce Jancin

For your adult patients with type 2 diabetes



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 $\geq 5\%$ 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.

metastatic breast cancer in 13 countries on five continents.

The following were among the key findings of the BRIDGE survey:

► One-half of women with metastatic breast cancer (MBC) believed that the condition receives too little public attention from the media, government, and celebrities. This was particularly true of Polish MBC patients, 76% of whom thought MBC receives too little attention, as well as patients in the United States, Canada, and Argentina, roughly two-thirds of whom held that view. They thought that early-stage breast can-

cer gets disproportionate attention, and they would particularly like to see more media stories on celebrities and everyday people who are living with MBC.

► Rates of participation in clinical trials ranged from a high of 35% for Canadian and Mexican women with MBC to a low of single-digit percentages among women in Brazil, France, and Venezuela. In all, 20% of women with MBC in the United States participated in clinical trials.

► Only 23% of MBC patients have ever been invited by a health care provider to consider participation in a clinical trial. Of these, 69% elected to do so. The most

common reasons for declining were fear of side effects, anticipated lack of benefit, desire not to be part of an experiment, and failure to meet screening requirements.

► Worldwide, 26% of women with MBC have searched proactively for information on clinical trials, as have 52% of Americans with MBC. One-third of these information-seeking women have enrolled in a clinical trial, compared with 12% of those who haven't actively sought out information.

► The most valuable aid cited by trial participants in getting through a clinical trial was support from their physician.

► Of U.S. women with MBC, 70% indicated that they found it easy to locate information that helps them cope with their disease.

► Three-quarters of surveyed women worldwide said they were still able to enjoy life despite having MBC. This was true of 90% of U.S. MBC patients, and of 91% in Australia and Venezuela, 93% in Brazil, 95% in Canada, and 99% in Argentina.

In general, the 52% of women whose first diagnosis was early-stage breast cancer rather than MBC had a more positive outlook on life. ■

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
- Broad formulary coverage nationally[†]
 - Accessible to almost 75% of patients[†]

Drug Interactions: Because ketoconazole, a strong CYP3A4/5 inhibitor, increased saxagliptin exposure, the dose of ONGLYZA should be limited to 2.5 mg when coadministered with a strong CYP3A4/5 inhibitor (e.g., atazanavir, clarithromycin, indinavir, itraconazole, ketoconazole, nefazodone, nelfinavir, ritonavir, saquinavir, and telithromycin).

Patients with Renal Impairment: The dose of ONGLYZA is 2.5 mg once daily for patients with moderate or severe renal impairment, or with end-stage renal disease requiring hemodialysis (creatinine clearance [CrCl] ≤50 mL/min). ONGLYZA should be administered following hemodialysis. ONGLYZA has not been studied in patients undergoing peritoneal dialysis. Assessment of renal function is recommended prior to initiation of ONGLYZA and periodically thereafter.

Pregnant and Nursing Women: There are no adequate and well-controlled studies in pregnant women. ONGLYZA, like other antidiabetic medications, should be used during pregnancy only if clearly needed. It is not known whether saxagliptin is secreted in human milk. Because many drugs are secreted in human milk, caution should be exercised when ONGLYZA is administered to a nursing woman.

Pediatric Patients: Safety and effectiveness of ONGLYZA in pediatric patients have not been established.

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

[†]"Patients" means covered lives as calculated by Fingertip Formulary[®] as of 10/09.

Please read the adjacent Brief Summary of the Product Information.

For more information about ONGLYZA visit www.onglyza.com.

Reference: 1. Fingertip Formulary[®] data as of October 25, 2009. Data on File, October 2009.

 Bristol-Myers Squibb

©2009 Bristol-Myers Squibb 422US09AB12927 12/09
Onglyza[™] is a trademark of Bristol-Myers Squibb

AstraZeneca 

294546