Metastatic Breast Cancer Patients Rarely in Trials

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 ERpositive 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.

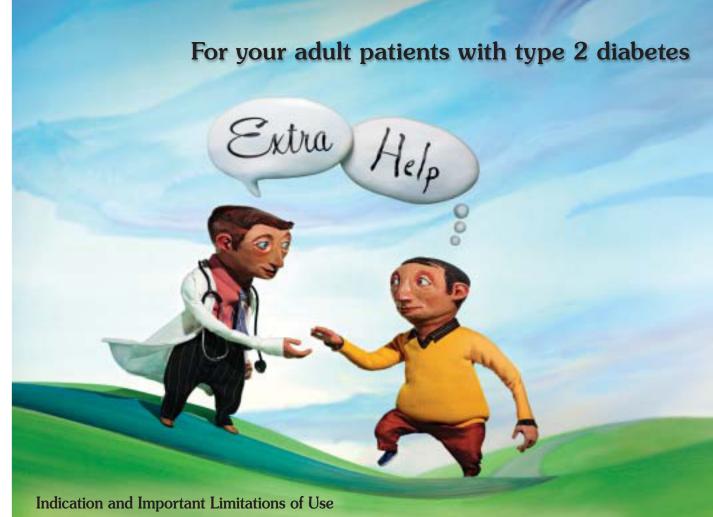
Fifty-three percent of patients in this series had a low Oncotype DX recurrence score below 18, another 38% had an intermediate score, and 9% had a recurrence score of 31 or more.

A separate survey presented in San Antonio involved the medical oncologists, surgeons, and pathologists for 154 consecutive women with early-stage, ERpositive 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



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.