Pharmacology Spotlight at ONS Congress

BY SARAH DIGIULIO

NEW ORLEANS—The first day of the Oncology Nursing Society's 37th Annual Congress wrapped up with a session highlighting noteworthy newly approved pharmacologic agents, recently expanded indications for pharma agents already available, and the FDA's response to critical drug shortages seen in the past year.

The following 11 agents have been recently approved by the FDA, noted Natalie Christine Mandolfo, MSN, APRN-NP, AOCN, a nurse practitioner at Nebraska Cancer Specialists, who also provided information on how to dose the treatments and possible side effects.

- **Crizotinib** is approved for treatment of patients with locally advanced or non-small cell lung cancer that is anaplastic lymphoma kinase-positive.
- **Peginterferon alfa-2b** is approved as an adjuvant treatment of melanoma with microscopic or gross nodal involvement within 84 days of definitive surgical resection including completion lymphadenectomy.

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immunotherapies with improved long-term survival outcomes, she said. After being on vemurafenib, some patients have success with ipilimumab.

Clinical trials are ongoing to test the effectiveness of a combination of BRAF and MEK inhibitors, or a combination of PD1 antibodies and a BRAF inhibitor (***OT, 6/10/12***). The theory is to eliminate the next pathway, to try to completely eliminate any pathway the tumor cells could grow along, Rubin said.

Understanding Side Effects

Oncology nurses should also be able to educate patients about the side effects profile of BRAF inhibitors, which can be unique. "The molecularly targeted therapies have associated 'off-target' or ancillary effects on surrounding cell-signaling pathways."

One of the more common side effects, for example, can be squamous cell carcinoma, she noted. Patients should be advised to look for new skin lesions (any wart-like spot, or skin change that doesn't seem to heal—often bumpy or scaly), and schedule an evaluation by a dermatologist if noticed. The lesions can develop on any skin surface, so even non-sun-exposed areas, such as the vulva, the cervix, and the genitals should be examined, Rubin said.

KRISTA RUBIN, MS, RN, FNP, BC: "Understanding the basics of these inhibitors—why there's resistance, what the next step is—is absolutely crucial for oncology nurses to be able to communicate with their patients."

Another side effect is extreme sun-sensitivity, so patients should be advised to be extra vigilant about using sunscreen and to stay in the shade whenever possible. And, since vemurafenib is associated with prolongation of the QTC interval, EKG testing is recommended for patients on other medications that also prolong the QTC.

"It's also important to educate patients that they must report any medications they are using, both prescription and non-prescription, and any kind of alternative therapies—vitamins, minerals, herbals—so that risks of toxicity will be minimalized," Rubin said.

She concluded the ONS session by emphasizing the role of the oncology nurse in helping patients understand how the drug works—the role it can play, and also the limitations of the drug. "We as nurses need to understand what's happening so we can bring the information down to a patient level."

Despite the drug's shortcomings, the excitement among the melanoma community is not unwarranted, she said. "Even though we're seeing maybe not durable responses, we are seeing something that at least is understandable. Understanding this signaling pathway really gives us an understanding of how melanoma works and grows."

Hyperlinks!

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- **Ipilimumab** (a human cytoxic T-lymphocyte antigen 4-blocking antibody) is indicated for the treatment of unresectable or metastatic melanoma.
- **Vemurafenib** (a kinase inhibitor) is indicated for the treatment of patients with unresectable or metastatic melanoma with BRAFV600E mutation.
- **Abiraterone** is approved for use in combination with prednisone for treatment of patients with metastatic castration-resistant prostate cancer who have received prior chemotherapy containingd ocetaxel.
- **Brentuximab** is approved for treatment of patients with Hodgkin lymphoma after failure of autologous stem cell transplantation or after at least two prior multi-agent chemotherapy regimens in patients who are not candidates for autologous stem cell transplants.
- **Vandetenib** (a kinase inhibitor) is approved for treatment of symptomatic or progressive medullary thyroid cancer in patients with unresectable locally advanced or metastatic disease.
- **Asparaginase *Erwinia chrysanthemi*** (an asparagine-specific enzyme) is approved as a component of a multi-agent chemotherapeutic regimen for the treatment of patients with acute lymphoblastic leukemia who have developed hypersensitivity to E. coli-derived asparaginase.
- **Axitinib** (a kinase inhibitor) is approved for treatment of advanced renal cell carcinoma after failure of one prior systemic therapy.
- **Vismodegib** is approved for treatment of adults with metastatic basal cell carcinoma, or with locally advanced basal cell carcinoma that has recurred following surgery or who are not candidates for surgery, and who are not candidates for radiation.
- **Ruxolitinib** (a kinase inhibitor) is approved for treatment of patients with intermediate- or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis, and post-essential thrombocythemia myelofibrosis.

Expanded Indications

Also at the session, Colleen Lemoine, APRN, MN, AOCN, RN-BC, Clinical Nurse Specialist for Oncology Professional Development, Practice Excellence and Clinical Affiliations at Interim Louisiana State University Public Hospital, discussed expanded indications for currently approved therapeutic agents, including:

- **Levoleucovorin**, for use in combination chemotherapy with fluorouracil (5-FU) in the palliative treatment of patients with advanced metastatic colorectal cancer.
- **Everolimus**, for the treatment of patients with progressive neuroendocrine tumors of pancreatic origin that are unresectable, locally advanced, or metastatic.
- **Sunitinib**, for treatment of progressive, well-differentiated pancreatic neuroendocrine tumors in patients with unresectable locally advanced or metastatic disease.
- **Cetuximab**, for use in combination with platinum-based therapy with 5-FU for the first-line treatment of patients with recurrent locoregional disease or metastatic squamous cell carcinoma of the head and neck.

New Supportive Care Agents

Lemoine also cited the following supportive care agents, newly approved by the FDA:

- **Denosumab** is indicated as a treatment to increase bone mass in men at high risk for fracture receiving androgen-deprivation therapy for nonmetastatic prostate cancer, and in women at high risk for fracture who are receiving adjuvant aromatase inhibitor therapy for breast cancer.
- **Fentanyl Sublingual spray** and **Fentanyl Citrate**, for management of breakthrough pain in cancer patients older than age 18 who are already receiving, and who can tolerate, opioid therapy for their underlying persistent cancer pain.
- **Glucarpidase**, for treatment of patients with toxic plasma methotrexate concentrations (more than 1 micromole per liter) in patients with delayed methotrexate clearance due to impaired renal function.

Drug Shortages

Lemoine also noted the following actions by the Food and Drug Administration related to the current drug shortages:

- In response to the critical shortage of Doxil, the FDA is allowing the immediate temporary importation and distribution of Lipodox, manufactured by Sun Pharma Global.
- In response to the critical shortage of methotrexate, the FDA has approved a preservative-free generic methotrexate, manufactured by APP Pharmaceuticals.
- The FDA had approved a Supplemental New Drug Application for imatinib mesylate for the adjuvant treatment of adult patients following complete resection of Kit-positive gastrointestinal stromal tumors, after the agent had initially been granted accelerated approval for the indication in 2008.