HOSPITAL PHARMACY ADMINISTRATION

HPA Newsletter

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FDA grants accelerated approval to new treatment (rucaparib) for advanced ovarian cancer

- The U.S. Food and Drug Administration today granted **accelerated approval to Rubraca (rucaparib) to treat women with a certain type of ovarian cancer.** Rubraca is approved for women with advanced ovarian cancer who have been treated with two or more chemotherapies and **whose tumors have a specific gene mutation (deleterious BRCA)** as identified by an FDA-approved companion diagnostic test.
  "Women with these gene abnormalities who have tried at least two chemotherapy treatments for their ovarian cancer now have an additional treatment option."
- The National Cancer Institute estimates that 22,280 women will be diagnosed with ovarian cancer in 2016 and an estimated 14,240 will die of this disease. Approximately 15 to 20 percent of patients with ovarian cancer have a BRCA gene mutation.
- BRCA genes are involved with repairing damaged DNA and normally work to prevent tumor development. However, mutations of these genes may lead to certain cancers, including ovarian cancers. Rubraca is a poly ADP-ribose polymerase (PARP) inhibitor that blocks an enzyme involved in repairing damaged DNA. By blocking this enzyme, DNA inside the cancerous cells with damaged BRCA genes may be less likely to be repaired, leading to cell death and possibly a slowdown or stoppage of tumor growth.
- **The NGS test,** which has been approved by FDA detects the presence of deleterious BRCA gene mutations in the tumor tissue of ovarian cancer patients. If one or more of the mutations are detected, the patient may be eligible for treatment with Rubraca.
- **The recommended starting dosage of rucaparib is 600 mg taken orally twice daily with or without food.** Treatment should continue until the cancer progresses or unacceptable toxicity occurs. - See more at: http://www.ashp.org/menu/News/PharmacyNews/NewsArticle.aspx?id=4388#sthash.dNnvsFdj.dpuf
- **Common side effects of Rubraca** include nausea, fatigue, vomiting, low levels of red blood cells (anemia), abdominal pain, unusual taste sensation (dysgeusia), constipation, decreased appetite, diarrhea, low levels of blood platelets (thrombocytopenia) and trouble breathing (dyspnea). Rubraca is associated with serious risks, such as bone marrow problems (myelodysplastic syndrome), a type of cancer of the blood called acute myeloid leukemia and fetal harm.
- The labeling states that a complete blood count should be performed before initiating rucaparib therapy and monthly thereafter. Rucaparib treatment should not be initiated until after hematologic abnormalities caused by previous chemotherapy have resolved.

References:

1-FDA grants accelerated approval to new treatment for advanced ovarian cancer [Internet]. Fda.gov. 2017 [cited 1 January 2017]. (Click Here)

2. News Article : Rucaparib Approved as Targeted Monotherapy for Advanced Ovarian Cancer [Internet]. Ashp.org. 2017 [cited 1 January 2017]. (Click Here)

Special points of interest:

- Latest disease updates
- Latest drugs updates

Inside this issue:

Long-term oxygen treatment does not benefit some COPD patients

Purpose:

To determine whether long-term oxygen treatment is beneficial for group of people with chronic obstructive pulmonary disease (COPD) and moderately low levels of blood oxygen.

Background :

COPD, the third leading cause of death in the United States, is a progressive lung disease triggered primarily by cigarette smoking, although up to 20 percent of patients with COPD never smoked. Symptoms include shortness of breath, chronic coughing, and wheezing. The disease also causes low oxygen levels in the blood. About 15 million people have been diagnosed with COPD in the United States and another 10 million may be undiagnosed.

For decades, oxygen has been one of the main treatment tools for patients with COPD and low oxygen levels. It involves the use of metal tank cylinders containing oxygen or concentrators that extract oxygen from air; both systems deliver the gas through a nasal tube or mask

The LOTT study is a randomized clinical trial to determine whether oxygen use could help COPD patients with moderately low levels of blood oxygen. The 738 patients enrolled in this study had COPD and moderately low levels of blood oxygen (in contrast to severely low blood oxygen levels) at rest or during exercise.

How does this study define moderately low levels of blood oxygen and severely low levels of blood oxygen:

- In the LOTT study, patients with **moderately low levels of blood oxygen** are defined as those with a blood oxygen saturation (peripheral capillary oxygen saturation, or SpO2) between 89 and 93 percent at rest (moderate resting hypoxemia), or a SpO2 below 90 percent during an exercise test, the 6-minute walk test.
- Patients with **severely low levels of blood oxygen** are defined as those with a SpO2 equal to or less than 88 percent at rest. This later group was excluded from the LOTT study because prior studies showed that they benefit from long-term oxygen treatment.
- Blood oxygen saturation or SpO2 refers to the percentage of oxygen-saturated hemoglobin relative to total hemoglobin in the blood and is measured through a pulse oximeter. A pulse oximeter is a special probe that indirectly measures oxygen levels in the blood, often by attachment to the finger

Results :

In the study, half of the patients received long-term oxygen and the other half did not. **The researchers found no significant differences between the two groups based on how long patients survived, and the amount of time leading to their first hospitalization. They also found no differences in other important benchmarks,** such as the rates at which the patients were hospitalized or experienced worsening of COPD symptoms. Nor did researchers find statistically significant differences between the groups in quality of life, levels of depression or anxiety, lung function, or ability to walk for short periods.

Although no cure for COPD exists, there are a number of treatment options, including the use of bronchodilators and steroids, as well as pulmonary rehabilitation, surgery, and lung transplantation. Researchers worldwide are also studying new medications and exploring other approaches such as gene therapy. They continue to emphasize the importance of not smoking tobacco in preventing or slowing the progression of COPD.

References:

Long-term oxygen treatment does not benefit some COPD patients - NHLBI, NIH [Internet]. Nhlbi.nih.gov. 2017 [cited 5 January 2017]. (Click Here)

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Our Newsletter

The Hospital Pharmacy Administration Newsletter aims to publicize up-to-date news, information, resources, and recent healthcare topics that have an impact on the patient's quality of care in addition to practices serving physicians and pharmacists. A main goal of this publication is to send our news and updates on health care drug related issues, recently reported and have direct impact on Clinical and Hospital Pharmacy practice in Egypt.

Hospital Pharmacy Administration (HPA)

Vision

To implement and spread clinical awareness among our hospital pharmacists to ensure better patient quality of care.

Mission

To manage and assure that hospital pharmacists meet each individual patient's drug-related needs through provision of pharmaceutical care services.

Goals and Objectives

Increase awareness of hospital Pharmacists on the importance of applying clinical knowledge in their pharmacy practice through:

- Plotting an appropriate pharmaceutical care plan for each patient according to his medication use strategy.
- Helping healthcare team through promptly responding to drug information requests.
- Integrating patient counseling into the process of dispensing.

NO HARMe

NO HARMe is a national voluntary medication error and 'near miss' reporting program founded for the purpose of sharing the learning experiences from medication errors. Implementation of preventative strategies and system safeguards to decrease the risk for error-induced injury and thereby promote medication safety in healthcare is our collaborative goal.

NO HARMe guarantees confidentiality and security of information received

To report a medication error to NO HARMe:

- Visit our website: www.eda.mohealth.gov.eg or,
- Email us at: medication.errors.system@gmail.com

WHEREVER THE ART OF MEDICINE IS LOVED, THERE IS ALSO A LOVE FOR HUMANITY