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推荐文章

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FDA：帕妥珠单抗被批准用于HER2阳性乳腺癌患者

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FDA: 帕妥珠单抗被批准用于HER2阳性乳腺癌患者

中国肿瘤化疗 来源：医脉通 发布日期:2012-6-18

一种治疗HER2阳性乳腺癌的新药-帕妥珠单抗(Pertuzumab，商品名Perjeta，罗氏)被美国FDA批准。2012年6月8日，罗氏（Roche）旗下基因泰克（Genentech）宣布，新的乳腺癌药物Perjeta已获FDA批准，用于HER-2阳性乳腺癌患者的治疗。大约有四分之一的乳腺癌患者是HER2阳性。

帕妥珠单抗应与第一代靶向HER2的单克隆抗体曲妥珠单抗（赫赛汀/罗氏）以及化疗药多西他赛联用。它用于治疗既往未接受过任何化疗或HER2靶向疗法的转移性HER2阳性的乳腺癌患者。

FDA主要是基于对CLEOPATRA的3期临床试验结果优先审查而做出上述决定的。目前相似的申请正在被欧洲药品局审查中。

这些结果在2011年12月12月的圣安东尼奥乳腺癌会议上发布，发表在《新英格兰医学杂志》上（NEJM. 2012;366:109-119）。

在CLEOPATRA试验中，同单纯曲妥珠单抗+多西他赛相比，加用帕妥珠单抗后，患者的进展生存率明显升高。（18.5：12.4个月;危险比0.62;P < .001）

在当时，整体生存数据并不成熟，但倾向于帕妥珠单抗。曲妥珠单抗+赫赛汀+化疗药的死亡率是17.2%，而赫赛汀+化疗药的死亡率则是23.6%。

上述3种药物组合具有“最小副作用”，非常安全且耐受性良好。

与赫赛汀的协同作用

“赫赛汀被批准应用已经超过10年时间，进一步的研究使我们更好地理解HER2在乳腺癌中的作用”，来自美国FDA药品评价与研究中心血液肿瘤内科产品办公室主任Richard Pazdur博士说道。

“这项研究提供了2种靶向药物联合的背景…，以及联合多西他赛来减缓乳腺癌进展”，当Pazdur博士批准帕妥珠单抗时说道。

当单独应用帕妥珠单抗测试时，它只表现了适度的抗肿瘤活性。然而，当同赫赛汀联合时则显示了其协同作用。虽然二者都是通过刺激细胞介导细胞毒性的单克隆抗体，但却作用在HER2不同点上。由于二者具有轻度不同的作用机理，二者合用能“更全面地封锁HER2信号，产生更大的抗肿瘤活性”，Baselga解释道。

分析人士指出：优先审查、帕妥珠单抗的批准预示着罗氏的另一种靶向

药物-T-DM1也将迎来春天。它是由赫赛汀与衍生自一种强大的化疗药物组成，用于HER2阳性乳腺癌的治疗。

FDA approves Perjeta for type of late-stage breast cancer

The U.S. Food and Drug Administration today approved Perjeta (pertuzumab), a new anti-HER2 therapy, to treat patients with HER2-positive late-stage (metastatic) breast cancer.

Intended for patients who have not received prior treatment for metastatic breast cancer with an anti-HER2 therapy or chemotherapy, Perjeta is combined with trastuzumab, another anti-HER2 therapy, and docetaxel, a type of chemotherapy.

HER2 is a protein involved in normal cell growth. It is found in increased amounts on some types of cancer cells (HER2-positive), including some breast cancers. In these HER2-positive breast cancers, the increased amount of the HER2 protein contributes to cancer cell growth and survival.

Perjeta is a humanized monoclonal antibody, manufactured through biotechnology methods. It is administered intravenously and is believed to work by targeting a different part of the HER-protein than trastuzumab, resulting in further reduction in growth and survival of HER2-positive breast cancer cells.

Because there are production issues that potentially could affect the long-term supply of the drug, FDA limited its approval today to drug product that has not been affected by those issues. Genentech, the manufacturer of Perjeta, has committed to take steps designed to resolve these production issues in a timely manner.

“Given the need for additional treatments for metastatic breast cancer, we made the decision to approve this drug today and not to delay its availability to patients pending resolution of the production issues relating to future supply,” said Janet Woodcock, M.D., director of FDA’s Center for Drug Evaluation and Research. “Genentech is currently developing a plan to mitigate the effect on patients of any potential shortage of Perjeta.”

Breast cancer is the second leading cause of cancer-related death among women. This year an estimated 226,870 women will be diagnosed with breast cancer, and 39,510 will die from the disease. About 20 percent of breast cancers have increased amounts of the HER2 protein.

“Since trastuzumab was first approved more than a decade ago, continued research has allowed us to better understand the role HER2 plays in breast cancer,” said Richard Pazdur, M.D., director of the Office of Hematology and Oncology Products in the FDA’s Center for Drug Evaluation and Research. “This research provided the background to combine two targeted drugs – trastuzumab and Perjeta with docetaxel to slow disease progression in breast cancer.”

The safety and effectiveness of Perjeta were evaluated in a single clinical trial involving 808 patients with HER2-positive metastatic breast cancer who were tested prior to treatment to determine if the HER2 protein was increased. Patients were randomly assigned to receive Perjeta, trastuzumab and docetaxel or trastuzumab and docetaxel with a placebo.

The study was designed to measure the length of time a patient lived without the cancer progressing, progression-free survival (PFS). Those treated with the combination containing Perjeta had a median PFS of 18.5 months, while those treated with the combination containing placebo had a median PFS of 12.4.

The most common side effects observed in patients receiving Perjeta in combination with trastuzumab and docetaxel were diarrhea, hair loss, a decrease in infection-fighting white blood cells, nausea, fatigue, rash, and nerve damage (peripheral sensory neuropathy).

Perjeta is being approved with a Boxed Warning alerting patients and health care professionals to the potential risk of death or severe effects to a fetus. Pregnancy status must be verified prior to the start of Perjeta treatment.

The therapy was reviewed under the agency’s priority review program, which provides for an expedited six-month review of drugs that may offer major advances in treatment.

Perjeta is marketed by South San Francisco-based Genentech, a member of the Roche Group.

上一篇:6程吉西他滨加紫杉醇一线化疗有效的转移性乳腺癌患者接受维持化疗或观察的疗效比较：一项III期多中心随机临床试验（KCSG-BR0702研究）结果报道
下一篇:紫杉类为基础的化疗加拉帕替尼或曲妥珠单抗一线治疗HER2阳性转移性乳腺癌的疗效比较：III期开放性随机临床试验（NCIC CTG MA.31/GSK EGF 108919）的中期分析结果报道

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