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乳腺癌试验药物palbociclib获“突破性药物”资格

作者：[中国肿瘤化疗] 来源：[本站] 浏览：[] 评论：[]

乳腺癌试验药物**palbociclib**获“突破性药物”资格

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美国监管机构(FDA)已授予辉瑞公司乳腺癌试验药物“突破性药物”资格，辉瑞公司股票应声上涨，其正在增长的癌症药物研发前景一片光明。JP摩根的分析称这种口服的抗癌药palbociclib能够为辉瑞公司带来50亿美元甚至更多的市场份额。这款药物可用于乳腺癌或其他类型癌症的治疗。

随着该药获得批准，辉瑞公司的股价应声上涨2.6个百分点，由于先前palbociclib的研究取得不错的临床结果，此次获得FDA特殊地位认定也是顺理成章的事情，现在辉瑞公司正在开展其III期临床研究。

今年初，FDA对被认为有可能证明比现有药物有“实质性改善”的新药设立“突破性药物”资格，意在加速这类药物的开发和审批。Leerink Swann分析员Seamus Fernandez称palbociclib到2020年每年可带来24亿美元的销售额。他预言当前研究会证实palbociclib可延缓肿瘤生长并延长生存。

JPMorgan分析员Chris Schott称FDA的这一决定对辉瑞股票注入了强心剂并预言由于“突破性药物”指定的助推作用，palbociclib将于2016年或更早一点获得批准。

在临床3期试验中，以局部晚期或转移性乳腺癌初治患者的试验对象，研究人员对Palbociclib以标准药物来曲唑为对照进行评估。辉瑞称稍早的中期试验的中期分析显示联合治疗的患者无症状恶化的平均时间为26.1个月，与之相比仅使用来曲唑的的患者这一数据为7.5个月。palbociclib的作用机理是通过组织CDK4和CDK6两种细胞周期蛋白依赖性激酶来起效。

辉瑞公司在过去的十年一直立志于研发出创新性的新药，其推出的肺癌药物Xalkori、肾癌的药物Inlyta和白血病治疗药Bosulif也确实为他赢回了不少市场。

Pfizer cancer drug wins special status;shares jump

(Reuters) - U.S. regulators have granted a"breakthrough therapy" designation to an experimental Pfizer Inctreatment for breast cancer, lifting the company's shares and putting aspotlight on its growing cancer-drug portfolio.

Analysts from JPMorgan and Leerink Swannforecast the oral medicine, called palbociclib, could generate annual sales of$5 billion or more if it is approved for use against breast cancer as well asother types of cancer.

Pfizer, whose stock rose 2.6 percent, saidthe U.S. Food and Drug Administration conferred the special status onpalbociclib based on impressive results seen in mid-stage trials. The drug isnow being tested in a larger Phase III study.

The FDA created the "breakthroughtherapy" designation earlier this year for medicines de emed likely todemonstrate "substantial improvement" over existing drugs. It isintended to speed development and regulatory review of such medicines.

Leerink Swann analyst Seamus Fernandez saidpalbociclib could generate annual sales of $2.4 billion by 2020 if it isapproved for breast cancer. He predicted the current study wo uld show palbociclibslows tumor growth and prolongs life.

JPMorgan analyst Chris Schott called theFDA decision a "clear positive for Pfizer shares" and predictedpalbociclib will be approved by 2016 or sooner thanks to acceleration unde r the"breakthrough" designation.

Palbociclib is being tested in combinationwith a standard drug, letrozole, in a Phase III tri al of patients undergoinginitial treatment for locally advanced or metastatic breast cancer.

Pfizer said interim data from the earliermid-stage trials showed patients on the combined t herapy went an average 26.1months without a worsening of symptoms, compared with 7.5 months for patientstaking only letrozole.

Palbociclib works by blocking two enzymes:cyclin dependent kinases (CDK) 4 and 6.

Pfizer, which has struggled in the pastdecade to come up with important new medicines, h as won respect with recentapprovals of three cancer drugs: Xalkori for lung cancer, Inlyta for kidneycancer and Bosulif for leukemia.

Pfizer shares were up 77 cents to $29.88 inearly-afternoon trade, outpacing a 1.2 percen t rise for the ARCA PharmaceuticalIndex of large U.S. and European drugmakers.

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