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FDA：软组织肉瘤治疗药物Pazopanib获批

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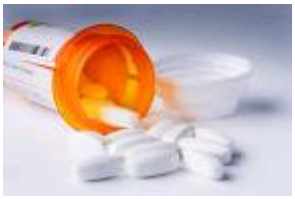
FDA：软组织肉瘤治疗药物Pazopanib获批



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2012年4月26日，美国食品与药物管理局（FDA）批准Pazopanib（帕唑帕尼，商品名 Votrient ）用于既往接受化疗的晚期软组织肉瘤患者。软组织肉瘤是一种源于肌肉、脂肪、纤维组织和其他组织的恶性肿瘤。

Pazopanib(帕唑帕尼)是葛兰素史克（GSK)研发的一种口服的可干扰血管生成的VEGF-2抑制剂，该药物还同时针对血小板衍化生长因子受体（PDGFR）和干细胞因子受体（c-kit）。软组织肉瘤是一种罕见的癌症，有很多亚型，在美国每年约有10,000例。超过20种亚型的肉瘤被纳入中临床试验中，这些试验结果导致了Pazopanib的批准。该药物还未被批准用于脂肪软组织肉瘤和胃肠道间质瘤。

FDA药品评价和研究中心血液和肿瘤学办公室的主人Richard Pazdur讲到，软组织肉瘤的新药批准在几十年来还是第一次，肉瘤的新药研发非常具挑战性，因为病人数量有限，但类型众多。

Pazopanib的安全和疗效在一项临床研究中得以评估，该研究纳入了369名既往接受化疗的晚期软组织肉瘤病人。病人随机分配接受Pazopanib或安慰剂治疗。主要终点是无进展生存期，Pazopanib为4.6个月，安慰剂组为1.6个月。

接受Pazopanib治疗的患者常见的不良反应包括疲乏，腹泻，恶心，呕吐，食欲下降，体重下降，高血压，肿瘤部位和肌肉疼痛，毛发颜色改变，头痛，味觉改变，呼吸困难和皮肤褪色。

Pazopanib的黑框警告提醒患者和卫生保健人员，该药有肝脏损伤的潜在危险，有可能是致命的损伤；应监测患者的肝功能，并且一旦出现肝功能下降应停止该药的治疗。

Pazopanib被指定为治疗晚期软组织肉瘤的孤儿药。Pazopanib首次获批上市是在2009年10月，用于治疗晚期肾癌。

FDA approves Votrient for advanced soft tissue sarcoma

The U.S. Food and Drug Administration today approved Votrient (pazopanib) to treat pa

tients with advanced soft tissue sarcoma who have previously received chemotherapy. So ft tissue sarcoma is a cancer that begins in the muscle, fat, fibrous tissue, and other tissues.

Votrient is a pill that works by interfering with angiogenesis, the growth of new blood vess els needed for solid tumors to grow and survive.

A rare cancer with many subtypes, soft tissue sarcoma occurs in about 10,000 cases ann ually in the United States. More than 20 subtypes of sarcoma were included in the clinical trial leading to approval of Votrient. The drug is not approved for patients with adipocytic soft tissue sarcoma and gastrointestinal stromal tumors.

“Soft tissue sarcomas are a diverse group of tumors and the approval of Votrient for thi s general class of tumors is the first in decades,” said Richard Pazdur, M.D., director of the Office of Hematology and Oncology Products in the FDA’s Center for Drug Evalua tion and Research. “Drug development for sarcomas has been especially challenging be cause of the limited number of patients and multiple subtypes of sarcomas.”

The safety and effectiveness of Votrient was evaluated in a single clinical study in 369 pati ents with advanced soft tissue sarcoma who had received prior chemotherapy. Patients w ere randomly selected to receive Votrient or a placebo. The study was designed to measu re the length of time a patient lived without the cancer progressing (progression-free survi val). The disease did not progress for a median of 4.6 months for patients receiving Votri ent, compared with 1.6 months for those receiving the placebo.

The most common side effects in Votrient-treated patients were fatigue, diarrhea, nausea, weight loss, high blood pressure, decreased appetite, vomiting, tumor and muscle pain, ha ir color changes, headache, a distorted sense of taste, shortness of breath, and skin discol oration.

Votrient carries a boxed warning alerting patients and health care professionals to the pot ential risk of liver damage (hepatotoxicity), which can be fatal. Patients should be monitor ed for liver function and treatment should be discontinued if liver function declines.

Votrient was granted an orphan drug status designation for this indication. An orphan desi gnation is given to a drug intended to treat a disease affecting fewer than 200,000 patients in the United States. Votrient was first approved in October 2009 for the treatment of ad vanced kidney cancer.

Votrient is marketed by GlaxoSmithKline of Research Triangle Park, N.C.

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