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FDA警告：来那度胺可增加第二原发癌风险

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FDA警告：来那度胺可增加第二原发癌风险

中国肿瘤化疗 来源: 环球医学网 发布日期: 16:01 2012-6-1

环球医学据悉，FDA警告称，来那度胺（Revlimid）作为多发性骨髓瘤的维持治疗与第二原发癌的风险增加相关。

FDA称，在三项试验中，新近诊断为多发性骨髓瘤的患者最初接受化疗和造血干细胞移植，然后接受来那度胺维持性治疗或安慰剂，结果显示，第二原发癌的风险增加了约三倍。

FDA还称，在涉及复发性/难治性患者（该药最初获批正是基于此人群）的试验中，在校正患者用药时长之后，并未显示第二原发癌的风险有所增加。

3项试验的合并分析显示，截至2011年2月28日，824例接受来那度胺治疗的患者中出现65例第二原发恶性肿瘤，非来那度胺治疗组的665例患者中则出现19例。

发病率分别为7.9%和2.8%，具有显著性差异， $P < 0.001$ 。

FDA报告称，这些第二原发癌包括急性髓细胞白血病、骨髓增生异常综合征和B细胞恶性肿瘤；整体而言，30例第二原发血液系统恶性肿瘤与来那度胺相关，相比之下，未服用来那度胺者中仅有2例。

FDA表示，非黑色素瘤皮肤癌或实体瘤的发病率似乎并无差异。

FDA还表示，将会修订来那度胺的标签和患者用药指南，以反映第二原发癌的风险增加。

FDA建议，患者和医生应当权衡来那度胺所带来的获益与其第二原发癌风险，而且医生应当密切监测服用来那度胺的患者。（环球医学）

原文:

FDA: Revlimid Linked to Second Cancers

Treatment of multiple myeloma with lenalidomide (Revlimid) as maintenance therapy is associated with an increased risk of second primary cancers, the FDA warned.

In three trials involving newly diagnosed patients initially treated with chemotherapy and stem cell transplantation, followed by maintenance lenalidomide or a placebo, the risk of a second primary cancer was increased about threefold, the agency said.

Trials involving relapsed/refractory patients - on which the drug's initial approval was based - did not show a significant increase in risk after adjustment for the length of time patients took the drug, the agency said.

A pooled analysis of the three maintenance trials showed that, as of Feb. 28, 2011, there had been 65 second primary malignancies among 824 lenalidomide patients and 19 among 665 patients in the treatment arms that did not include the drug.

The difference in incidence -- 7.9% versus 2.8% -- was significant at $P < 0.001$.

The second primary cancers included acute myelogenous leukemia, myelodysplastic syndromes, and B-cell malignancies, the FDA reported, and, overall, 30 second primary hematologic malignancies were associated with lenalidomide, compared with two among patients not getting the drug.

There appears to be no difference in the incidence of nonmelanoma skin cancers or of solid tumors, the agency said.

The agency said the drug's label and patient medication guide will be amended to reflect the increased risk.

Patients and physicians should balance the benefit of the drug with the increased risk of second primary cancers, the agency suggested, and doctors should monitor patients on lenalidomide closely.

相关链接: <http://www.medpagetoday.com/HematologyOncology/Myeloma/32576>

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