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On Drugs and Therapeutics

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IN BRIEF

Ponatinib (*Iclusig*) Marketing and Sales Suspended

The FDA recently issued a Drug Safety Communication saying that it had asked the manufacturer of ponatinib (*Iclusig* – Ariad) to suspend marketing and sales of the drug because of the risk of life-threatening blood clots and severe narrowing of blood vessels.¹ Ponatinib is a tyrosine kinase inhibitor that was granted accelerated approval by the FDA in December 2012 for treatment of chronic-, accelerated, or blast-phase chronic myeloid leukemia (CML) and Philadelphia chromosome-positive (Ph+) acute lymphoblastic leukemia (ALL) resistant to (or the patients were intolerant to) prior tyrosine kinase inhibitor therapy. It is the first tyrosine kinase inhibitor that is effective against the T315I mutation, which is present in up to 20% of patients with treatment-resistant CML.²

The labeling of *Iclusig* includes a warning about the risk of arterial thrombosis, but recent clinical trial results showed an unexpectedly high incidence of serious adverse vascular events, some fatal, which occurred in 24% of patients in one clinical trial with a median duration of 1.3 years and 48% in another with a median duration of 2.7 years. These adverse events occurred in some patients as early as 2 weeks after starting ponatinib. Neither trial included a control group. Blindness has occurred in some patients and in one of the trials, 8% of those treated with the drug developed heart failure.

Suspension of marketing and sales does not necessarily mean that *Iclusig* will be withdrawn permanently; it is the only option available for some treatment-resistant patients.³ The drug could be returned to the market, possibly with new labeling narrowing the selection of patients, lowering the dosage, or recommending use of aspirin concomitantly to decrease the risk of thrombosis.⁴

1. FDA Drug Safety Communication: FDA asks manufacturer of the leukemia drug Iclusig (ponatinib) to suspend marketing and sales. Available at www.fda.gov/Drugs/DrugSafety/ucm373040.htm. Accessed November 18, 2013.
2. Ponatinib (Iclusig) for CML and Ph+ ALL. *Med Lett Drugs Ther* 2013; 55:71.
3. JH Doroshow. Overcoming resistance to targeted anticancer drugs. *N Engl J Med* 2013; 369:1852.
4. Ariad expects narrower label, not withdrawal, for Iclusig following halted study. "The Pink Sheet" 2013; 75:16.

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