

NCCN Chronic Myelogenous Leukemia Guidelines V.1.2011 – Update Teleconference – 07/06/10

Guideline Page and Request	Panel Discussion	References	Include in Guideline	
			YES	NO
<p>CML-1 Internal request: Update guideline based on 2009 ASH presentations, recent publications related to nilotinib and dasatinib for primary therapy.</p> <p>External request: Submission from Novartis Oncology.</p>	<p>Two separate phase III, randomized trials are comparing nilotinib [Evaluating Nilotinib Efficacy and Safety in Clinical Trials Newly Diagnosed Patients (ENESTnd)] and dasatinib [Dasatinib versus Imatinib Study in Treatment-Naive CML Patients (DASISION)] versus imatinib for newly diagnosed patients with chronic-phase Philadelphia chromosome-positive CML. At a minimum follow-up of 12 months, the rates of major molecular response and complete cytogenetic response were significantly higher for nilotinib and dasatinib as compared to imatinib. The rate of disease progression to accelerated or blast phase was also significantly lower for nilotinib and dasatinib compared to imatinib. The panel added nilotinib or dasatinib as options for primary therapy of patients with newly diagnosed CML with a category 1 level designation for each agent.</p>	<ol style="list-style-type: none"> 1. Saglio G, Kim D, Issaragrisil S, et al. Nilotinib versus imatinib for new diagnosed chronic myelogenous leukemia. <i>N Engl J Med</i> 2010;362:2251-2259. 2. Kantarjian H, Shah NP, Hochhaus A, et al. Dasatinib versus imatinib in newly diagnosed chronic-phase chronic myeloid leukemia. <i>N Engl J Med</i> 2010;362:2260-2270. 3. http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/022068s004s005lbl.pdf 	14	0
<p>CML-2, CML-3, CML-4, CML-5, CML-6, CML-7</p>	<p>The panel recommends that the choice of nilotinib or dasatinib as options in follow-up therapy should be dependent on the TKI that was used as primary therapy.</p>		14	0