



March 03, 2008

Steve Phurrough, MD, MPA  
Centers for Medicare & Medicaid Services  
Coverage and Analysis Group  
Mailstop C1-09-06  
7500 Security Boulevard  
Baltimore, MD 21244

Re: CMS recognition of the NCCN Drug Biologics Compendium

Dear Dr. Phurrough:

ImClone Systems Incorporated (ImClone Systems) requests, as part of the open comment period, that the Center for Medicare & Medicaid Services (CMS) add the National Comprehensive Cancer Network Drugs & Biologics Compendium (NCCN Compendium) to the list of compendia specified in Section 1861(t)(2)(B)(ii)(I) of the Social Security Act. This section lists certain compendia recognized by CMS and allows CMS to name additional compendia for recognition.

### **ImClone Systems**

ImClone Systems Incorporated is a biopharmaceutical company committed to advancing oncology care by developing and commercializing a portfolio of targeted biologic treatments designed to address the medical needs of patients with a variety of cancers. The Company's research and development programs include growth factor blockers and angiogenesis inhibitors. The company's first approved product, Eribitux® (cetuximab), has been approved by the Food and Drug Administration for the treatment of irinotecan refractory or intolerant EGFR-expressing metastatic colorectal cancer and for locally advanced, recurrent or metastatic head and neck cancer.

### **NCCN Compendium**

As outlined in the Federal Register of November 27, 2007, the NCCN Compendium appears to satisfy the CMS definition of a compendium. The NCCN Compendium is a comprehensive listing of cancer chemotherapeutics and biologics that provides information on recommended uses in specific cancers, dose and schedules for administration and links to pharmacology data for every compound. In addition, it is our understanding that the NCCN Compendium was scored very positively by the Medicare Evidence Development and Coverage Advisory Committee (MedCAC) regarding the established attributes of a desirable compendium.

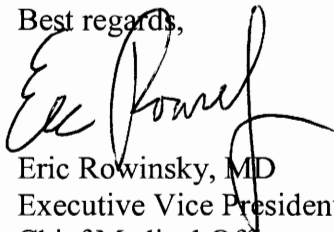
NCCN has established a sound model for review of emerging clinical evidence by recognizing that appropriate medical indications are not always supported by the gold standard of evidence (e.g., prospective, double-blinded clinical studies). Consequently, NCCN's editorial panels use a consensus process based on an analysis of the most pertinent data available and on expert knowledge. NCCN's process results in expert recommendations with the expectation that new evidence may or not validate those recommendations in the future. As such, NCCN routinely reviews all of its expert recommendations. NCCN's standard of review of innovative anti-cancer therapies reflects the flexibility needed to promote appropriate access to promising new treatments without setting the bar for approval low and at the expense of patient safety.

**Conclusion**

The NCCN Compendium appears to satisfy CMS' and MedCAC's criteria for a compendium. Its continual updating, transparent review of submitted clinical literature, clear reporting of recommendations and free web access assures ease of use and timely access for patients to quality cancer drug and biologic care. Given this, ImClone Systems requests that CMS add the NCCN Compendium to the list of compendia specified in Section 1861(t)(2)(B)(ii)(I) of the Social Security Act.

If you have any questions regarding ImClone System's request, please feel free to contact me at [eric.rowinsky@imclone.com](mailto:eric.rowinsky@imclone.com) or 908-203-6912.

Best regards,



Eric Rowinsky, MD  
Executive Vice President  
Chief Medical Officer