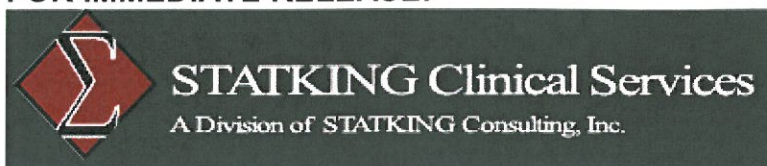


**FOR IMMEDIATE RELEASE:**



## **STATKING Provides Clinical Services Support For Women's Health Drug**

Cincinnati, OH – May 24, 2011 – STATKING Clinical Services, a provider of clinical trials services, made significant contributions to the successful approval of Xanodyne Pharmaceutical's Lysteda® drug for heavy menstrual bleeding in women, now divested to Ferring Pharmaceuticals. STATKING provided the following key inputs for this development program:

- Negotiated with FDA personnel on the statistical strategy issues during the program
- Planned and implemented all databases and data management plans for the individual studies and the combined safety and efficacy analyses
- Answered FDA data questions during the NDA's expedited review

In addition, STATKING's statistical programming staff generated a total of 1,094 data analysis tables based on over 90,000 lines of SAS code that were sent to FDA as part of the Lysteda submission while the STATKING data management staff created and populated databases containing data from 236,814 case report forms from 1,585 subjects enrolled in the four pivotal trials used in the submission. STATKING project managers supervised the creation and archiving of 71 internal and external process documents and conducted over 150 meetings between the client and the STATKING staff to move the project forward.

### **About STATKING Clinical Services**

STATKING Clinical Services provides clinical trial services (biostatistics, clinical data management, clinical study monitoring, medical writing, safety reporting, project management and clinical trial management) for clinical trials for the regulatory approval of novel drug and medical device products. The company is headquartered in Fairfield, OH. The company has provided support on 12 NDAs and 13 PMAs over the past two decades of service to the pharmaceutical and medical device industries. For more information, visit [www.statkingclinical.com](http://www.statkingclinical.com).

### **About Xanodyne Pharmaceuticals**

Xanodyne Pharmaceuticals, Inc. is an integrated specialty pharmaceutical company with both development and commercial capabilities focused on pain management. For more information, visit [www.xanodyne.com](http://www.xanodyne.com).

### **Contact**

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