

Contacts: Investors EVC Group Douglas Sherk, 415-896-6820 Jennifer Beugelmans, 646-201-5447

Media EVC Group Jen Saunders 646-201-5431

## FOR IMMEDIATE RELEASE

## Pharsight Uses FDA Disease Model to Support Oncology Drug Development Use of FDA Model in Non-Small Cell Lung Cancer Expected to Inform Quantitative Predictions for Experimental Cancer Treatment

MOUNTAIN VIEW, Calif., November 20, 2007 – Pharsight Corporation (OTC Bulletin Board: PHRS), a leading provider of software, strategic consulting, and regulatory services for optimizing clinical drug development, today announced that its Strategic Consulting Services Group is using a quantitative disease model developed by the Food and Drug Administration (FDA) for non-small cell lung cancer (NSCLC) to support an oncology drug development program sponsored by one of its clients, a global pharmaceutical company.

Pharsight scientists are using FDA's publicly available model in NSCLC to perform simulations of expected survival based on tumor shrinkage for an investigational drug in early clinical studies. Pharsight scientists also expect to refine these simulations with emerging data in new clinical studies to assist with key oncology development program decisions, including optimized dose selection and improved design of survival trials.

Pharsight's collective modeling and simulation experience in oncology includes longitudinal exposure-response modeling to inform labeling decisions and test dosing strategies, allometric projections, and work with novel mechanisms.

FDA has developed several quantitative drug-disease models based on the literature and clinical trial data from sponsor submissions for drug approval. FDA does not release proprietary source data from sponsors used to develop and validate the models, but the agency has underscored its commitment to publicly sharing and further testing the models that it has developed in important disease areas, including oncology. The NSCLC model was presented by FDA scientists at a January 2007 meeting, co-sponsored by FDA and the Drug Information Association (DIA), entitled "Sharing Knowledge to Improve Clinical Drug Development and Regulatory Decisions: Data/models of Diseases, Drugs, Placebo, Baseline, and Dropouts." Additional information can be found at <a href="https://www.diahome.org">www.diahome.org</a> or requested from FDA at <a href="mailto:pharmacometrics@fda.hhs.gov">pharmacometrics@fda.hhs.gov</a>.

"As outlined in FDA's Critical Path Initiative, model-based drug development offers an important approach to improving drug development knowledge management and decision-making," said Shawn O'Connor, president, chief executive officer, and chairman of Pharsight. "We are pleased that FDA has shared their NSCLC survival model with the public to describe prior knowledge in this area. With our unmatched collective modeling expertise, Pharsight

scientists are uniquely positioned to help our clients build, adapt, and extend drug-disease models in their own development programs. Over the past three years, we have supported more than 30 oncology programs and modeling initiatives for industry clients, from pre-clinical to Phase III and covering critical issues in trial design, dose selection, and development strategy. We look forward to collaborating with our client to share feedback with FDA, and to contributing to ongoing industry discussions on opportunities for sharing drug-disease models to support quantitative decision-making in clinical development."

## **About Pharsight Corporation**

Pharsight Corporation develops and markets integrated products and services that enable pharmaceutical and biotechnology companies to achieve significant and enduring improvements in the development and use of therapeutic products. Pharsight's goal is to help customers reduce the time, cost and risk of drug development, as well as optimize the post-approval marketing and use of pharmaceutical products.

Pharsight's approach enhances the fundamental element of drug development success: strong decision-making. By adopting the Pharsight approach, customers acquire a new decision-making process with the potential to systematically improve every level and phase of their business and scientific processes. Pharsight Corporation is headquartered in Mountain View, California. Information about Pharsight is available at <a href="https://www.pharsight.com">www.pharsight.com</a>.

## **Registered Trademarks and Trademarks**

Pharsight is a registered trademark of Pharsight Corporation. All other brand or product names mentioned in this documentation are trademarks or registered trademarks of their respective companies or organizations.