

Valera Pharmaceuticals Files an IND to Commence Clinical Studies of a Long-Acting Naltrexone Implant for Opioid Addiction

Cranbury, N.J., June 27, 2006 . Valera Pharmaceuticals, Inc. (NASDAQ:VLRX) today announced it submitted an Investigational New Drug Application (IND) to the Food and Drug Administration (FDA) for VP004, a subdermal implant utilizing Valera's Hydron technology to deliver naltrexone, over an extended period of time, for the treatment of opioid addiction.

With this IND having been submitted, Valera said it is now preparing for a Phase I/II, open label study of its naltrexone implant in healthy volunteers with a history of opioid abuse. A primary objective of this study is to investigate the extent of opiate blockade following morphine challenges. The lead investigator is the pioneering addiction researcher and renowned authority on naltrexone, Donald Jasinski, M.D., Professor of Medicine, Chief Center for Chemical Dependence, Johns Hopkins Bayview Medical Center.

At this stage of development, it is not possible to predict with certainty the duration of time over which our naltrexone implant will deliver a therapeutic dose of the active agent, said David S. Tierney, M.D., Valera's President & CEO. However, our goal is an implant that can provide controlled release of naltrexone for three to six months. We believe such a product would offer significant advantages over the currently approved daily oral formulation of naltrexone for treating opioid dependence, particularly with regard to patient compliance.

Approved by the FDA in the early 1980s as a daily oral medication for treating heroin addiction, naltrexone is a potent opioid receptor antagonist that binds to receptors in the brain, thus, blocking the euphoric effects produced by opioids. However, as an oral tablet administered once daily, this treatment for drug abuse has faced a serious patient compliance issue, because most patients forget or deliberately choose not to take their medicine.

Drug abuse and addiction is a major public health problem that encompasses nonmedical uses of approved opioid analgesics, including prescription pain relievers, such as hydrocodone, oxycodone and morphine as well as the addictive use of heroin, an illegal opioid. According to the National Survey on Drug Use and Health (NSDUH), as reported by the Substance Abuse and Mental Health Services Administration, Office of Applied Sciences (<http://oas.samhsa.gov>), 2.4 million persons aged 12 and older initiated nonmedical use of prescription pain relievers in 2004. Additionally, the NSDUH estimates that over 100,000 persons used heroin for the first time in 2004, the average age of the initiates being 24.4 years.

Furthermore, among the estimated 16.4 million illicit drug users aged 18 or older in 2004, 12.3 million (75.2 percent) were employed either full or part time. The National Institute of Drug Abuse (www.nida.nih.gov) notes that employed drug abusers cost employers about twice as much in medical and worker compensation claims compared to drug-free workers. Additionally, a report, The Economic Cost of Drug Abuse in the United States, developed for the Executive Office of the President, Office of National Drug Control Policy (2001 Publication No. NCJ-190636), estimates the total economic cost of drug abuse, including healthcare expenses, productivity losses, and other costs to society such as crime and social welfare increased from approximately \$100 billion in 1992 to over \$140 billion in 1998.

Dr. Tierney noted, The filing of the IND for our naltrexone implant represents an important milestone achievement for Valera. We believe the successful completion of this development program will extend Valera's platform technology into a large market for treating opioid abuse and addiction.

About Valera Pharmaceuticals

Valera Pharmaceuticals is a specialty pharmaceutical company focused on developing, acquiring, and commercializing products to treat urology and endocrinology diseases and disorders. Utilizing its innovative Hydron technology, Valera is developing soft, compact and flexible hydrogel-based implants which can be designed to release therapeutic agents at a controlled rate for up to twelve months. VANTAS(R), a patent protected once-per-year implant currently marketed by Valera for the palliative treatment of advanced prostate cancer, employs this drug delivery technology. Additional information about Valera Pharmaceuticals is available at: <http://www.valerapharma.com>.

This press release contains forward-looking statements that are not historical facts but rather are based on current expectations, estimates and projections about the Company's industry, beliefs and assumptions. Words such as "anticipates," "expects," "intends," "plans," "believes," "seeks" and "estimates," and variations of these words and similar expressions, are intended to identify forward-looking statements. These statements are not guarantees of future performance and are subject to risks, uncertainties and other

factors, some of which are beyond the Company's control, are difficult to predict and could cause actual results to differ materially from those expressed, implied or forecasted in the forward-looking statements. These risks and uncertainties include, among others, those described in "Risk Factors" contained in the Company's Form 10-K as filed with the Securities and Exchange Commission on March 20, 2006. You are cautioned not to place undue reliance on these forward-looking statements as actual future results and events may be materially different from what the Company currently expects. The forward-looking statements included in this press release reflect the Company's views and assumptions only as of the date of this press release. Except as required by law, the Company undertakes no obligation to update any forward-looking statement, whether as a result of new information, future events, or otherwise.

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