

## Valera Pharmaceuticals Submits NDA for SUPPRELIN-LA, a 12- Month Implant for the Treatment of Central Precocious Puberty

Cranbury, N.J., July 6, 2006 . Valera Pharmaceuticals, Inc. announced it submitted a New Drug Application (NDA) to the Food and Drug Administration (FDA) for SUPPRELIN(R)-LA, a 12-month implant for central precocious puberty (CPP), or the early onset of puberty in children.

More prevalent in girls, CPP is characterized by the premature development of secondary sexual characteristics in young children due to increased secretion of sex hormones. In addition to social and psychological concerns, the disorder, if left untreated, limits a child from attaining full adult height, thus, resulting in short stature.

In November 2005, the FDA granted SUPPRELIN-LA orphan drug designation which provides seven years marketing exclusivity from the date of marketing approval as well as certain economic benefits and tax credits. In addition, Valera noted that SUPPRELIN-LA is the second product to emerge from its pipeline that utilizes its proprietary and patent protected Hydron technology. The first, VANTAS(R), is a once-per-year implant for advanced prostate cancer which was approved by the FDA in October 2004.

This NDA submission marks a major milestone for Valera, said David S. Tierney, M.D., President & CEO. With the potential commercialization of SUPPRELIN-LA in 2007, we anticipate having at least three products on the market next year. In addition to our currently marketed VANTAS, this includes VALSTAR(R), the only approved drug therapy for certain urinary bladder cancer patients, which we recently acquired and expect to launch around year-end 2006.

SUPPRELIN-LA has been designed to provide the continuous 12-month administration of a controlled dose of histrelin, a potent synthetic nonapeptide agonist of naturally occurring gonadotropin-releasing hormone (GnRH). The standard of care of CPP involves the use of such GnRH agonists to suppress hormonal production to delay the onset of puberty. SUPPRELIN, as a daily injection, was previously approved by the FDA and marketed in the 1990s to treat CPP. Valera acquired the rights to the brand name earlier this year.

The U.S. CPP therapy market is currently estimated at over \$75 million annually. The market is dominated by Lupron Depot-PED(R) (leuprolide acetate for depot suspension) from TAP Pharmaceutical Products, Inc. which involves intramuscular injections administered to afflicted children every four weeks. In general, depending on the age of the child at the time of diagnosis, CPP hormonal therapy could run three to five years, or longer.

We believe a 12-month implant offers an attractive treatment option for CPP patients, their parents, and the pediatric endocrinologists who treat these children, said Dr. Tierney. Also, from a marketing point of view, SUPPRELIN-LA represents an excellent growth opportunity for Valera, because this therapeutic space is not crowded with competitors and consists of a concentrated physician audience of a few hundred specialists.

The multi-center, open-label Phase III study of SUPPRELIN-LA, which is the basis of the NDA submission, involved 36 patients ranging in age from four to eleven years. Sixteen children had received GnRH therapy prior to enrollment while the remaining twenty were naïve to treatment. The subcutaneous implant was inserted into the inner aspect of the upper arm. Primary endpoints were hormonal suppression below pubertal levels and continued suppression upon challenge with gonadotropin-releasing hormone. All patients were analyzed for efficacy and safety.

The outcome of any FDA review can never be assured, concluded Dr. Tierney. However, we are very encouraged by the clinical data and optimistic about the prospects for SUPPRELIN-LA.

### 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. 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," "potential" 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. In addition, the forward-looking events discussed in this press release might not occur. 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. You should read the Company's Form 10-K, and the documents that the Company refers to therein and have filed as exhibits with the understanding that 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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Contact:  
Valera Pharmaceuticals  
Stuart Z. Levine, Ph.D.  
Director, Investor Relations  
609-409-9010 Ext. 3202  
[slevine@valerapharma.com](mailto:slevine@valerapharma.com)