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**PAR PHARMACEUTICAL ANNOUNCES FDA APPROVAL OF MEGACE<sup>®</sup> ES FOR ANOREXIA, CACHEXIA, OR AN UNEXPLAINED, SIGNIFICANT WEIGHT LOSS IN PATIENTS WITH A DIAGNOSIS OF AIDS**

**WOODCLIFF LAKE, NJ** (July 6, 2005) – Par Pharmaceutical Companies, Inc. (NYSE: PRX) today announced that the U.S. Food and Drug Administration (FDA) has approved Megace<sup>®</sup> ES (megestrol acetate), a concentrated oral suspension for the treatment of anorexia, cachexia, or an unexplained, significant weight loss in patients with a diagnosis of acquired immunodeficiency syndrome (AIDS). The approval of Megace ES represents the first branded pharmaceutical product developed by Par to be approved for marketing by the FDA. New Megace ES is an advanced formulation of megestrol acetate oral suspension, the appetite stimulant most commonly prescribed by physicians. Megace ES can be taken without regard to meals and is dosed at one-fourth the volume of the original product.

“Unintended weight loss and cachexia, also known as wasting, have been shown to be determining factors in progression of disease in AIDS patients,” said Lynn Kramer, MD, senior vice president, clinical development and medical affairs. “For patients who have difficulty swallowing a large dose, or those with a lack of appetite who cannot eat without the help of medication, the approval of Megace ES is a crucial advance.”

Megace ES utilizes Elan’s NanoCrystal<sup>®</sup> Technology delivery system\* to improve the rate of dissolution and bioavailability of the original megestrol acetate oral suspension. Recent data have shown that the bioavailability of the original formulation is reduced substantially when taken on an empty stomach. With Megace ES, this reduction in bioavailability is minimized in the fasted state, resulting in improved bioavailability in patients who have not eaten. Megace ES 625 mg/5 mL and megestrol acetate oral suspension 800 mg/20 mL are bioequivalent in a fed state.

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\*NanoCrystal Technology is a trademark of Elan Pharma International Limited.

Patients taking Megace ES will be able to take a one-teaspoon (625 mg/5 mL) daily dose, or one-fourth of the volume of the original product. Previously, patients had to drink one 20 mL cup (800 mg/20 mL) of megestrol acetate oral suspension daily to receive the drug's full benefit. Megace ES also is 16 times less viscous (10 cP versus 163 cP) than the original formulation.

"Par Pharmaceutical is committed to the science of improving treatment solutions for patients," said Scott Tarriff, president and chief executive officer. "It is gratifying to be able to offer patients this advanced product. Improved bioavailability and reduced volume per dose of Megace ES should allow patients to receive the complete benefit of the therapy."

### **Efficacy of Megace ES**

The FDA approval of Megace ES was based on pharmacokinetic studies demonstrating bioequivalence between 625 mg of Megace ES and 800 mg of megestrol acetate oral suspension when dosed in a fed state. The clinical benefits of megestrol acetate oral suspension in treating patients with anorexia, cachexia, or an unexplained, significant weight loss have been clearly demonstrated in patients with AIDS. In one of two placebo-controlled, randomized efficacy trials in patients with AIDS, megestrol acetate oral suspension effectively stimulated appetite in nine out of 10 patients, increased mean caloric intake by 646 calories per day, and increased mean weight gain by 10.7 pounds versus placebo in 12 weeks. Patients also reported an improved sense of well being. In a second placebo-controlled study, seven out of 10 patients experienced improved appetite, mean caloric intake was increased by 464 calories a day, and mean weight increased by 13.3 pounds versus placebo.

Moreover, a bioavailability study directly comparing the rate and extent of absorption of Megace ES and megestrol acetate oral suspension revealed that the C<sub>max</sub>\*\* level with the original formulation was 1,364 ng/mL in fed patients and 187 ng/mL in unfed patients. In contrast, the C<sub>max</sub> level with Megace ES was 1,517 ng/mL in fed patients and 1,041 ng/mL in unfed patients. Further, in unfed patients Megace ES achieved 5 times greater peak plasma levels than megestrol acetate oral suspension. Additionally, the study demonstrated that a lower volume of Megace ES achieved maximum blood concentration more rapidly than the currently available oral suspension products.

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\*\* C<sub>max</sub>: Maximum drug concentration in blood plasma.

### **About Unintended Weight Loss**

Anorexia (a persistent lack of appetite), unintended weight loss, and cachexia (significant weight loss that involves depletion of both fat and lean body mass) represent a serious risk in patients with AIDS. Significant weight loss and cachexia are associated with worsening illness, physical impairment, decreased tolerance of some therapeutic agents, and increased susceptibility to infection.

### **Important Safety Information About Megace ES**

Megace ES and megestrol acetate oral suspension are contraindicated in patients with a history of hypersensitivity to megestrol acetate or any component of the formulation, or patients with known or suspected pregnancy.

Evidence of adrenal suppression has been observed in patients receiving megestrol acetate oral suspension. The glucocorticoid activity of megestrol acetate oral suspension has not been fully evaluated.

Clinical cases of new onset diabetes mellitus, exacerbation of pre-existing diabetes mellitus, and overt Cushing's Syndrome have been reported in association with the chronic use of megestrol acetate.

The most common adverse events ( $\geq 1\%$  and  $>$  than placebo) associated with Megace ES 625 mg/5 mL and megestrol acetate oral suspension 800 mg/20 mL are impotence, flatulence, rash, hypertension, insomnia, fever, decreased libido, dyspepsia and hyperglycemia.

Women who participated in studies (n=10) reported breakthrough bleeding; however, it is unknown if these events are drug- or disease-related. For more information on Megace ES, or for complete prescribing information, visit [www.MegaceES.com](http://www.MegaceES.com).

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### **About NanoCrystal Technology**

Megace ES was developed with NanoCrystal Technology, a nanoparticulate drug delivery system of Elan Pharma International Limited, a subsidiary of Elan Corporation, plc (NYSE: ELN). NanoCrystal Technology is applied exclusively to poorly water-soluble drugs, and has been applied successfully to several dosage forms to overcome many of the problems created by low levels of water solubility. An extensive patent estate protects Elan's NanoCrystal Technology. More information about Elan's NanoCrystal Technology is available at [www.elan.com/EDT](http://www.elan.com/EDT).

### **About Par Pharmaceutical Companies**

Par Pharmaceutical Companies, Inc. develops, manufactures and markets generic pharmaceuticals through its principal subsidiary, Par Pharmaceutical, Inc., and its recently acquired subsidiary, Kali Laboratories, Inc. The company also is developing an additional line of branded pharmaceutical products for specialty markets, the first of which is Megace ES. Par currently manufactures, markets or licenses 90 prescription drugs. The trade name Megace was licensed from Bristol-Myers Squibb Company. For press releases and other company information, visit [www.parpharm.com](http://www.parpharm.com).

*Certain statements in this press release constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. To the extent any statements made in this news release contain information that is not historical, these statements are essentially forward-looking and are subject to risks and uncertainties, including the difficulty of predicting FDA filings and approvals, acceptance and demand for new pharmaceutical products, the impact of competitive products and pricing, new product development and launch, reliance on key strategic alliances, uncertainty of patent litigation filed against us, availability of raw materials, the regulatory environment, fluctuations in operating results and other risks and uncertainties detailed from time to time in the Company's filings with the Securities and Exchange Commission, such as the Company's Form 10-K, Form 10-Q, and Form 8-K reports.*