



## NEWS RELEASE

### **Antares' Oxybutynin Gel Product Approved by FDA for the Treatment of Overactive Bladder**

*-- Novel Formulation Provides Convenience, Efficacy and Excellent Tolerability*

*-- Watson to Launch Product in Spring 2012 --*

PARSIPPANY, NJ and EWING, NJ – December 8, 2011 -- Watson Pharmaceuticals, Inc. (NYSE: WPI) and Antares Pharma, Inc. (NYSE Amex: AIS) today announced that the U.S. Food and Drug Administration (FDA) has approved Antares' topical oxybutynin gel 3% product for the treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and frequency. OAB is a condition that affects more than 33 million Americans, and the market currently exceeds \$2.0 billion annually.

Antares' oxybutynin product is a clear, odorless topical gel available in a convenient, metered-dose pump that has demonstrated to be an effective and safe treatment for overactive bladder (OAB). Because the active ingredient is delivered transdermally, it is not metabolized by the liver in the same way as orally administered oxybutynin. This results in a low level of side effects, such as dry mouth and constipation. Under an exclusive licensing agreement, Watson anticipates launching the product in 2012.

"This significant achievement represents Antares' first NDA approval and is the culmination of a development program managed successfully by our clinical and regulatory team," said Paul K. Wotton, Ph.D., Antares' President and CEO. "Watson Pharmaceuticals' proven track record of commercializing transdermal products to urologists and other significant prescribers of OAB treatments makes them an ideal partner to execute a successful product launch."

"The addition of Antares' oxybutynin gel product will strategically enhance our overactive bladder product portfolio which currently includes GELNIQUE® (oxybutynin chloride) Gel 10%, and OXYTROL® oxybutynin transdermal system," said Fred Wilkinson, Watson's Executive Vice President, Global Brands. "With the addition of Antares' new gel formulation, we look forward to offering patients the added convenience of a novel pump delivery system beginning in 2012."

### **About Antares' Oxybutynin Gel 3%**

Antares oxybutynin gel 3% is a topical, translucent hydroalcoholic gel containing oxybutynin, an antispasmodic, antimuscarinic agent. Applied once daily to the thigh, abdomen, upper arm or shoulder, an 84 mg (approx. 3 mL) dose delivers a consistent dose of oxybutynin through the skin over a 24-hour period, providing significant efficacy without sacrificing tolerability.

The approval of Antares' oxybutynin gel 3% is based on a 12-week, multi-center placebo controlled Phase 3 clinical study conducted by Antares. Patients were randomized to either an 84 mg or 56 mg dose application of oxybutynin gel 3% versus placebo. The FDA approved the 84 mg dose application. Patients treated with 84 mg oxybutynin gel daily achieved steady state drug concentrations within three days and experienced a statistically significant decrease in OAB symptoms versus placebo, including the number of urinary incontinence episodes per week. Statistically significant improvements in daily urinary frequency and urinary void volume were also seen with the 84 mg dose.

The product was well tolerated in the study. The most frequently reported treatment-related adverse events (>3%) were dry mouth (12.1% versus 5% in placebo), application site erythema (3.7% versus 1.0% in placebo) and application site rash (3.3% versus 0.5% in placebo).

Additional pharmacokinetic studies showed that showering one hour or later, or the application of sunscreen 30 minutes before or after gel application had no effect on the overall systemic exposure of the drug.

### **About Overactive Bladder (OAB)**

OAB is characterized by a sudden, uncomfortable need to urinate with or without urge incontinence (urine leakage), and usually includes more frequent urination and nocturia (waking up at least once during the night to urinate). It affects as many as 33 million adults in the U.S. – more than diabetes or asthma.

More than an “inconvenience,” OAB is disabling and associated with a marked decrease in health-related quality of life as well as higher rates of depression. The disease affects both men and women however, women experience more severe symptoms earlier in life.

### **About Antares Pharma**

Antares Pharma focuses on self-injection pharmaceutical products and topical gel-based medicines. The Company's subcutaneous and intramuscular injection technology platforms

include Vibex™ disposable pressure-assisted auto injectors, disposable multi-use pen injectors and Vision™ reusable needle-free injectors distributed as Tjet® and Zomajet® by Teva Pharmaceutical Industries, Ltd (Teva) and Ferring Pharmaceuticals (Ferring), respectively. In the injector area, Antares Pharma has a multi-product deal with Teva that includes Tev-Tropin® human growth hormone (hGH) and a partnership with Ferring that includes Zomacton® hGH. In the gel-based area, the Company's lead product candidate is Anturoi®, an oxybutynin ATD™ gel for the treatment of OAB (overactive bladder) which has been licensed to Watson Pharmaceuticals, Inc. for the U.S. and Canada. Antares' partnership with BioSante includes LibiGel® (transdermal testosterone gel) which is now in Phase 3 clinical development for the treatment of female sexual dysfunction (FSD), and Elestrin® (estradiol gel) indicated for the treatment of moderate-to-severe vasomotor symptoms associated with menopause, and currently marketed in the U.S. Antares Pharma has two facilities in the U.S. The Parenteral Products Division located in Minneapolis, Minnesota directs the manufacturing and marketing of the Company's reusable needle-free injection devices and related disposables, and develops its disposable pressure-assisted auto injector and pen injector systems. The Company's corporate offices and Pharma Division are located in Ewing, New Jersey, where pharmaceutical products are developed utilizing both the Company's transdermal systems and drug/device combination products.

#### **About Watson Pharmaceuticals, Inc.**

Watson Pharmaceuticals, Inc. is a leading integrated global pharmaceutical company. The Company is engaged in the development and distribution of generic pharmaceuticals and specialized branded pharmaceutical products focused on Urology and Women's Health. Watson has operations in many of the world's established and growing international markets. For press release and other company information, visit Watson Pharmaceuticals' Web site at <http://www.watson.com>.

#### **Forward-Looking Statement**

This communication contains forward-looking statements, including statements regarding the timing of product launch. These statements are indicated by the words “may,” “will,” “plans,” “intends,” “believes,” “expects,” “anticipates,” “potential,” “could,” “would,” “should,” and similar expressions. Such forward-looking statements involve known and unknown risks, uncertainties, and other factors that may cause actual results to differ materially from those projected in the forward-looking statements. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date on which they are made. Factors that might cause future results to differ include, but are not limited to, the following: difficulties or delays in manufacturing; the availability and pricing of third party sourced products and

materials; successful compliance with FDA and/or other governmental regulations applicable to manufacturing facilities, products and/or businesses; difficulty of predicting the impact of competitive products and pricing; changes in the laws and regulations, including Medicaid, and similar drug reimbursement laws; competitive economic and regulatory factors in the pharmaceutical and healthcare industry; the ability to obtain and enforce patents and other intellectual property rights; general economic conditions; and other risks and uncertainties that may be detailed, from time-to-time, in Watson's and Antares' reports filed with the SEC, including, but not limited to, their Annual Reports on Form 10-K for the year ended December 31, 2010 and Form 10-Q for the quarter ended September 30, 2011. Watson and Antares do not undertake any responsibility to revise or update any forward-looking statements contained herein, except as expressly required by law.

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**CONTACTS:**

**Watson**

Investors:  
Patty Eisenhour  
(862) 261-8141

Media:  
Charlie Mayr  
(862) 261-8030

**Antares**

Antares Pharma, Inc.  
Robert F. Apple  
Chief Financial Officer  
(609) 359-3020

Investors:  
Westwicke Partners, LLC  
John Woolford  
(443) 213-0506  
[john.woolford@westwicke.com](mailto:john.woolford@westwicke.com)

Media:  
Tiberend Strategic Advisors, Inc.  
Jason Rando  
(212) 827-0020  
[jrando@tiberendstrategicadvisors.com](mailto:jrando@tiberendstrategicadvisors.com)