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FOR IMMEDIATE RELEASE

**UPSHER-SMITH ANNOUNCES LAUNCH OF THE FIRST AND ONLY GENERIC
TRANSDERMAL TESTOSTERONE GEL AVAILABLE IN THREE CONVENIENT
CONFIGURATIONS**

***Testosterone Gel (1%), the Generic Equivalent to Vogelxo™ (testosterone) Gel, Expected
to Increase Access for Patients Who Need It***

Maple Grove, MN – July 2, 2014 – [Upsher-Smith Laboratories, Inc.](http://www.upsher-smith.com), today announced the launch of Testosterone Gel (1%), the generic of the newly Food and Drug Administration (FDA) approved Vogelxo™ (testosterone) gel 1%, for topical use, CIII, and the first and only available generic testosterone replacement therapy (TRT) available in three convenient configurations. Testosterone Gel (1%) offers once-daily dosing, 24-hour coverage and three configurations: unit-dose tubes and packets and metered-dose pumps. Vogelxo™ and Testosterone Gel are a prescription medicine that contains testosterone. Vogelxo™ and Testosterone Gel are used to treat adult males who have low or no testosterone and with conditions associated with low or no testosterone.

It is not known if Vogelxo™ and Testosterone Gel are safe or effective in children younger than 18 years old. Improper use of Vogelxo™ or Testosterone Gel may affect bone growth.

“At Upsher-Smith, we focus on driving measurable value, in dollars and outcomes, within the healthcare system. The generic availability of Testosterone Gel in three convenient configurations is an important advance in the testosterone replacement therapy marketplace and should greatly increase access for the patients who need it,” said Mark Evenstad, President and Chief Executive Officer of Upsher-Smith.

According to the American Urological Association, 39 percent of men over the age of 45 have low testosterone, but few are being treated.^{1,2} Methods of treatment vary in cost and convenience. Among them are injections, patches and gels. Testosterone Gel (1%) is supplied

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as unit-dose tubes and packets and metered-dose pumps. Each tube or packet contains 50 mg of testosterone in 5 g of gel. Each metered-dose pump delivers 12.5 mg of testosterone per complete pump actuation.

IMPORTANT SAFETY INFORMATION

Vogelxo™ and Testosterone Gel are controlled substances (CIII) because they contain testosterone, which can be a target for people who abuse prescription medicines. Keep your Vogelxo or Testosterone Gel in a safe place to protect it. Never give your Vogelxo or Testosterone Gel to anyone else, even if they have the same symptoms you have. Selling or giving away this medicine may harm others and it is against the law.

What is the most important information I should know about Vogelxo or Testosterone Gel? Early signs and symptoms of puberty have happened in young children who were accidentally exposed to testosterone through contact with men using Vogelxo or Testosterone Gel. Signs and symptoms of early puberty in a child may include:

- enlarged penis or clitoris
- early development of pubic hair
- increased erections or sex drive
- aggressive behavior

It is important that you apply Vogelxo or Testosterone Gel exactly as your healthcare provider tells you to. Vogelxo and Testosterone Gel can transfer from your body to others. Women and children should **avoid contact with the unwashed or unclothed area where Vogelxo or Testosterone Gel has been applied. If a woman or child makes contact with the Vogelxo or Testosterone Gel application area, that area on the woman or child should be washed well with soap and water right away.**

Stop using Vogelxo or Testosterone Gel and call your healthcare provider right away if you see any signs and symptoms in a child or a woman that may have occurred through accidental exposure to Vogelxo or Testosterone Gel.

- **Signs and symptoms of exposure to Vogelxo or Testosterone Gel in children may include:** enlarged penis or clitoris; early development of pubic hair; increased erections or sex drive; aggressive behavior
- **Signs and symptoms of exposure to Vogelxo or Testosterone Gel in women may include:** changes in body hair; a large increase in acne

To lower the risk of transfer of Vogelxo or Testosterone Gel from your body to others, you should follow these important instructions:

- **Apply Vogelxo or Testosterone Gel only to the areas of your shoulders and upper arms that will be covered by a short sleeve T-shirt.**
- **Wash your hands right away** with soap and water after applying Vogelxo or Testosterone Gel.
- **After the gel has dried, cover the application area with clothing.** Keep the area covered until you have washed the application area well or have showered.
- **If you expect to have skin-to-skin contact with another person, first wash the application area well with soap and water.**

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Do not use Vogelxo or Testosterone Gel if you: have breast cancer, or have or might have prostate cancer.

Vogelxo and Testosterone Gel are not meant for use in women. Do not use Vogelxo or Testosterone Gel if you are pregnant or may become pregnant or are breastfeeding. Vogelxo and Testosterone Gel may harm your unborn or breastfeeding baby. Women who are pregnant or who may become pregnant should avoid contact with the area of skin where Vogelxo or Testosterone Gel has been applied.

Before you use Vogelxo or Testosterone Gel, tell your healthcare provider if you: have breast cancer; have or might have prostate cancer; have urinary problems due to an enlarged prostate; have heart problems; have liver or kidney problems; have problems breathing while you sleep (sleep apnea); or have any other medical conditions.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Vogelxo and Testosterone Gel and certain other medicines you take can affect each other. Especially, tell your healthcare provider if you take: insulin, medicines that decrease blood clotting, or corticosteroids.

It is important that you apply Vogelxo or Testosterone Gel exactly as your healthcare provider tells you to. Your healthcare provider will tell you how much Vogelxo or Testosterone Gel to apply and when to apply it. Your healthcare provider may change your Vogelxo or Testosterone Gel dose. Do not change your Vogelxo or Testosterone Gel dose without talking to your healthcare provider. Vogelxo and Testosterone Gel are to be applied only to the areas of your shoulders and upper arms that will be covered by a short sleeve t-shirt. Do not apply Vogelxo or Testosterone Gel to any other parts of your body such as your penis, scrotum, or stomach area (abdomen).

Vogelxo and Testosterone Gel are flammable until dry. Let Vogelxo or Testosterone Gel dry before smoking or going near an open flame.

Vogelxo and Testosterone Gel can cause serious side effects including:

- **If you already have enlargement of your prostate gland your signs and symptoms can get worse while using Vogelxo or Testosterone Gel.** This can include: increased urination at night; trouble starting your urine stream; having to pass urine many times during the day; having an urge that you have to go to the bathroom right away; having a urine accident; being unable to pass urine or weak urine flow.
- **Possible increased risk of prostate cancer.** Your healthcare provider should check you for prostate cancer or any other prostate problems before you start and while you use Vogelxo or Testosterone Gel.
- **Blood clots in your legs or lungs.** Symptoms of a blood clot in your legs can include leg pain, swelling or redness. Symptoms of a blood clot in your lungs can include difficulty breathing or chest pain.
- **In large doses Vogelxo and Testosterone Gel may lower your sperm count.**
- **Swelling of your ankles, feet, or body, with or without heart failure.**
- **Enlarged or painful breasts.**
- **Having problems breathing while you sleep (sleep apnea).**

Call your healthcare provider right away if you have any of the serious side effects listed above.

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The most common side effects of Vogelxo and Testosterone Gel include: skin irritation where Vogelxo or Testosterone Gel are applied; increased red blood cell count; headache; and increased blood pressure.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

This safety information is not all-inclusive. For more information, talk to your health care provider and read the [Medication Guide](#) for patients and the [Full Prescribing Information](#), including the Boxed Warning regarding the risk of transfer to others. You can also visit www.upsher-smith.com or call 1-888-650-3789.

About Low Testosterone

Male hypogonadism (or low testosterone) is a condition in which the body does not produce enough testosterone – the hormone that plays a key role in masculine growth and development during puberty.³ Signs and symptoms associated with low levels of testosterone include: erectile dysfunction, decreased sexual desire, fatigue and loss of energy, mood depression, regression of secondary sexual characteristics and osteoporosis.^{4,5}

About Upsher-Smith

Upsher-Smith Laboratories, Inc., founded in 1919, is a growing pharmaceutical company dedicated to its mission of *Advancing Pharmacotherapy. Improving Life™*. With capabilities ranging from early-stage research to delivering on-market products, Upsher-Smith is committed to offering quality products that enable people to live life to its greatest potential. Upsher-Smith's approach to product development and partnering has resulted in a broad range of both branded and generic therapeutic solutions to address patients' needs. The Company has a particular focus on developing therapies for people living with central nervous system (CNS) conditions, such as seizure disorders, and has a robust pipeline of promising CNS compounds in various stages of development. For more information, visit www.upsher-smith.com.

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References

1. Urology Care Foundation. Low Testosterone (hypogonadism). <http://www.urologyhealth.org>. Accessed June 9, 2014.
2. Medscape.com. Available at: <http://www.medscape.com/viewarticle/721069>. Accessed June 16, 2014
3. Mayo Clinic. Male Hypogonadism. <http://www.mayoclinic.org/diseases-conditions/male-hypogonadism/basics/causes/con-20014235?p=1>. Accessed May 13, 2014.
4. Vogelxo [package insert]. Maple Grove, MN: Upsher-Smith Laboratories, Inc; 2014.
5. Testim [package insert]. Chesterbrook, PA: Auxilium Pharmaceuticals, Inc; 2014.

Vogelxo is a trademark of Upsher-Smith Laboratories, Inc.