**AMERICAN BOTANICAL COUNCIL**
P.O. Box 144345, Austin, TX 78714-4345
Phone: 512-926-4900 x121; Fax: 512-926-2345
Contact: Nancy Moon
Email: nancy@herbalgram.org
Web site: http://www.herbalgram.org/

*Editor's Note: Mark Blumenthal is available for interviews. Please contact Nancy Moon per above.*

**FOR IMMEDIATE RELEASE**

# *News Release*

## FDA Approves Special Green Tea Extract as a New Topical Drug for Genital Warts

### Expert Says Development Marks the Birth of a "New Industry"

Austin, Texas. (November 9, 2006) Last week the U.S. Food and Drug Administration (FDA) approved a special extract of green tea as a prescription drug for the topical (external) treatment of genital warts caused by the human papilloma virus (HPV). The new drug, called Veregen™ (Polyphenon® E) Ointment is the first prescription botanical (herbal) drug approved by FDA under the "new" drug amendments of 1962 that required drugs to be proven both safe and effective prior to being marketed in the U.S.

The active drug ingredient, Polyphenon® E, represents a proprietary mixture of phytochemicals produced from a partially purified water extract of green tea leaves. Green tea, brewed from the leaves of the tea plant (*Camellia sinensis*), is one of the most popular beverages worldwide. Unlike leaves used for black or oolong teas, leaves used to prepare "green" tea do not undergo a fermentation process. Therefore, green tea retains higher levels of highly antioxidant polyphenolic compounds known as catechins.

Polyphenon® E has been shown to have significant pharmacological activities when tested both internally and externally in animals and humans. For FDA drug approval, the safety and efficacy of Polyphenon® E Ointment were studied in two prospective, randomized, double-blind clinical studies in nearly 400 adults with external genital and anal warts ranging in number from 2 to 30. Test subjects applied the ointment three times daily until complete clearance of all warts. In each of these clinical trials, the median time to clear warts completely was 16 weeks and 10 weeks, respectively. Changes in the skin over the site of use were the most commonly reported side effects and included redness, itching, burning, pain/discomfort, ulceration, swelling, and local hardening of the skin. Polyphenon® E Ointment will be available in the United States only by prescription. While not a cure (new warts may develop following the ointment therapy), this new drug adds another proven intervention to be used in the treatment of warts, under the guidance

of a physician. The drug was developed by MediGene, a German company, and will be marketed in the United States by Bradley Pharmaceuticals of Fairfield, NJ.
"This is a regulatory breakthrough, said Mark Blumenthal, Founder and Executive Director of the nonprofit American Botanical Council. "It is the first time a complex herbal preparation has come to market as a prescription drug in the U.S. in more than half a century."

Freddie Ann Hoffman, MD, an expert on this botanical drug process, said, "A new drug industry has just been born -- perhaps 'reborn' -- in the United States: the *polymolecular* botanical drug industry." Dr. Hoffman is a former FDA official and is founder of HeteroGeneity, LLC, a Washington, D.C.-based consulting firm advising companies seeking to market botanically-based drugs.

"Though many within the FDA may not yet recognize it as such, this approval represents an historic milestone for the agency, she continued. "It is proof that FDA can deal with botanicals -- not only as foods and dietary supplements, but also as approved medicines." Dr. Hoffman added, it "will hopefully stimulate more serious research efforts regarding the clinical uses of botanicals. Manufacturers should also now be more willing to pursue a medical indication for their products, along with appropriate marketing claims."

Hoffman also views FDA's action as pivotal in addressing the nexus of an ongoing debate regarding the safe use of herbals for medical conditions. "Health professionals, insurance carriers, and consumers themselves must realize that this new drug is not a nutritional supplement or an 'alternative' therapy, but a mainstream therapy fully supported by clinical evidence of safety and efficacy equal to that of any chemical or biotechnology drug approved by FDA in the U.S. today. This approval indeed paves the way for a new pharmaceutical industry."

Whether or not a new class of botanical-- or "polymolecular"-- drugs will have cost benefits over synthetic or biotechnology products, Dr. Hoffman finds this too early to assess. "We will need to see more drug approvals before anyone can speculate on cost-savings of this drug class over others." She adds, "The fact, however, that botanicals find their uses out of learnings gleaned of other countries and cultures – from traditional, historical and even current use as foods and supplements-- should shorten their pathway to drug approval in the US."

FDA defines a "botanical" as a product that exclusively contains ingredients from plants, algae or fungi. In contrast to most conventional pharmaceutical drugs comprised of one single chemical, botanicals contain complex mixtures of naturally-occurring chemicals. In order to more appropriately evaluate herbal mixtures, in June 2004 the FDA published *Guidance for Industry for Botanical Drugs*, a new policy providing advice for potential botanical drug manufacturers, describing both the application process and providing recommendations as to how chemically complex products might satisfy the requirements of FDA's rigorous "new drug" review process.

**About Polyphenon E® Ointment**
Polyphenon E® Ointment, 15% is a botanical drug approved as a topical treatment of external genital and anal warts in adults. External genital warts, caused by human papilloma viruses (HPV type 6 or 11), are one of the most common and fastest-spreading venereal diseases worldwide. Scientists estimate that as many as 1 million new cases of genital warts are diagnosed in the United States each year. Approximately 14 million people in the United States and 15 million people in Europe are infected with HPV.

Polyphenon E® Ointment is a product of global development. In 1997, Epitome Pharmaceuticals Ltd., a privately owned Canadian company (Halifax, Nova Scotia) licensed from Mitsui Norin, Ltd. (Tokyo, Japan), a patented method of treating external genital warts through the topical application of Polyphenon E® green tea extract, the he patent for which extends through 2017. Epitome sublicensed the technology to MediGene AG of Munich, Germany, which collaborated in two multi-center Phase II clinical trials. In 2003 MediGene extended its license to include the treatment of hyperplasia caused by papilloma viruses. In 2004 MediGene conducted two Phase III trials, one in Europe and another in the Americas. Based on these trial results, MediGene submitted a New Drug Application (NDA) to the FDA Center for Drug Evaluation and Research in September 2005. FDA accepted the NDA for filing in early December 2005. MediGene reportedly plans to submit European marketing authorization applications for the drug before the end of 2006. MediGene is the first German biotech company to obtain marketing authorization for a drug in the United States.

MediGene predicts peak sales potential for Polyphenon® E Ointment of up to $100 million annually. The drug will be commercialized in the United States by MediGene's marketing partner, Bradley Pharmaceuticals, Inc. (NYSE: BDY), which is expected to launch the product during the second half of 2007. Both Bradley operating units will market Polyphenon E® Ointment, 15%, with the Doak Dermatologics subsidiary promoting the drug to dermatologists, and Bradley's Kenwood Therapeutics division marketing this topical therapy to obstetric and gynecological physicians.

**About the American Botanical Council**
Established in 1988, the American Botanical Council (ABC) is the leading nonprofit, member-based international organization working to educate consumers, healthcare professionals, researchers, educators, industry, and the media on the safe and effective use of herbs and medicinal plants products. ABC is located on a 2.5 acre site in Austin, Texas where it publishes *HerbalGram*, a peer-reviewed quarterly journal. ABC is also the publisher of *The ABC Clinical Guide to Herbs*, a continuing education and reference book, which contains extensive monographs on the safety and efficacy of 29 popular herbs, including green and black tea. ABC also just published *The Identification of Medicinal Plants: A Handbook of Morphology of Botanicals in Commerce*, a guide to the macroscopic identification of botanical materials for industry quality control laboratories. More information is available at http://www.herbalgram.org/.

###