## Agile Therapeutics Announces Appointment of Science Advisory Board Member

Former FDA Director of the Division of Reproductive and Urologic Products/CDER, Dr. Daniel A. Shames

Joins Agile Therapeutics Scientific Advisory Board

PRINCETON, N.J., Feb. 13, 2014 /PRNewswire— Agile Therapeutics, a specialty pharmaceutical company focused on women's health, announced today that Daniel A. Shames M.D., F.A.C.S., has joined its Scientific Advisory Board. Dr. Shames is an experienced clinician with extensive experience in pharmaceutical development and regulatory affairs. His experience includes over ten years of practice at the U.S. Food and Drug Administration (FDA) where he served as Deputy Director, Office of Drug Evaluation III/Center for Drug Evaluation and Research (CDER) from 2006 to 2008, as well as a member of the Senior Management Team of the Office of New Drugs and the Drug Safety Oversight Board. Since 2008, as President of Daniel A. Shames Consulting, Inc., he has been an independent clinical/regulatory consultant on a wide range of pharmaceutical issues. Dr. Shames began his career with the FDA in 1996 and held positions as Primary Medical Officer, Team Leader and Deputy Director in the Division of Reproductive and Urologic Products (DRUP). From 2001 to 2006, he served as Director of DRUP and reviewed therapeutic products for clinical areas including contraception, infertility, obstetrics, menopause and urinary incontinence for which he received the CDER Leadership Excellence Award. He later served as Director of the Division of Gastroenterology and Inborn Error Products from 2007 to 2008 where he received the FDA Outstanding Service Award for leadership.

"Dr. Shames brings to us a depth of expertise and will be an important source of advice on our clinical and regulatory strategies for our novel late-stage transdermal contraceptive product," said Dr. Elizabeth Garner, Chief Medical Officer of Agile Therapeutics. "We are honored that Dr. Shames has joined our Scientific Advisory Board and we look forward to his contributions as we continue on our path to provide new contraceptive options for patients and their healthcare providers."

Dr. Shames earned his medical degree from Georgetown Medical School, and completed his specialty training in the Urology Residency Program at the University of Pennsylvania and a Post-Doctoral Fellowship in renal research from the National Institutes of Health. Prior to joining the FDA, Dr. Shames was in private urology practice and on the clinical faculty at the University of South Carolina School of Medicine and, while at FDA, Georgetown Medical School. He is an author on numerous scientific papers published in peer-reviewed journals, and has received many distinguished awards and honors over the course of his career.

Dr. Shames will be joining other prominent members of Agile Therapeutics Scientific Advisory Board that include:

- David F. Archer, M.D.
   Professor of Obstetrics and Gynecology, Director, Reproduction, Endocrinology, and Infertility
   Fellowship Program, East Virginia Medical School and Jones Institute for Reproductive Medicine
- Daniel R. Mishell Jr., M.D.
   Professor, Department of Obstetrics and Gynecology, Keck School of Medicine, University of Southern California
- Frank Z. Stanczyk, Ph.D.
   Professor of Research, Departments of Obstetrics and Gynecology and Preventive Medicine, Keck School of Medicine, University of Southern California

Carolyn Westhoff, M.D.

Professor of Obstetrics and Gynecology Medical Director, New York Presbyterian Hospital
Family Planning Clinic and Columbia University Medical Center

## **About Agile Therapeutics**

Agile Therapeutics is a specialty pharmaceutical company focused on women's health that is currently developing innovative contraceptive products based on Agile's proprietary and patented transdermal technology called Skinfusion<sup>®</sup>. Skinfusion consists of both an active and a peripheral adhesive system designed to allow stable drug delivery and dependable adhesion over seven days. The Company's lead investigational product, Twirla<sup>TM</sup>(AG200-15), is a once-weekly contraceptive patch designed to provide convenience and compliance that is currently in late stage clinical development. Agile has an additional pipeline of product candidates consisting of innovative contraceptive patch regimens and a progestin-only contraceptive patch (AG890) that utilize Skinfusion. For more information, please visit http://www.agiletherapeutics.com.

## **Forward Looking Statements**

Certain matters discussed in this press release are "forward-looking statements". We may, in some cases, use terms such as "predicts," "believes," "potential," "continue," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. In particular, the Company's statements regarding trends and potential future results are examples of such forward-looking statements. The forward-looking statements include risks and uncertainties, including, but not limited to, the success, timing and cost of our ongoing clinical trials and anticipated clinical trials for our current product candidates, including statements regarding the timing of initiation and completion of the trials; the timing of and our ability to obtain and maintain U.S. Food and Drug Administration or other regulatory authority approval of, or other action with respect, to our product candidates; the Company's ability to successfully defend its intellectual property or obtain the necessary licenses at a cost acceptable to the Company, if at all; the successful implementation of the Company's research and development programs and collaborations; the success of the Company's license agreements; the acceptance by the market of the Company's products; and other factors, including general economic conditions and regulatory developments, not within the Company's control. The factors discussed herein could cause actual results and developments to be materially different from those expressed in or implied by such statements. The forward-looking statements are made only as of the date of this press release and the Company undertakes no obligation to publicly update such forward-looking statements to reflect subsequent events or circumstance.

###