Urovalve announces early successful results in 13 patients treated in clinical trial of its Surinate® Bladder Management System

Company expects to seek approval to market Surinate® in Europe upon completion of U.S. study

NEWARK, N.J., Oct. 5, 2010—Urovalve, a medical device company focused on creating superior products for urinary flow and control, reported today that early results are promising in a multi-site clinical study of the Company’s Surinate® Bladder Management System. The Surinate® Bladder Management System is designed to improve the quality of life and health of men who suffer from acute or chronic urinary retention, an inability to empty the bladder.

Proper insertion of the Surinate® catheter was successful in thirteen of the first fourteen subjects enrolled in the study. All 13 subjects were able to properly position and actuate the Surinate® device and empty their bladder successfully and use the Surinate® device successfully for more than 24 hours. Mean time that the inserted Surinate® device remained in place was 14.1 days to final visit and removal. There has been no evidence of irritation or injury to the urethra in any of these 13 subjects. Mild irritation of the bladder (...“less than commonly seen with a Foley”... according to the Investigator) was observed cystoscopically in two subjects after removal of the Surinate® catheter and one spinal cord injured subject exhibited formation of bladder stones, a common problem with Foley catheters in spinal cord patients, according to urologists.

“These early clinical results are extremely encouraging,” said Harvey D. Homan, Ph.D., President and CEO of Urovalve. “What we need to see going forward is patients who are able to have the Surinate® catheter remain in place for 30 consecutive days. We are confident that we will reach this important endpoint in the study.”

Urovalve believes that there is a significant unmet need in healthcare for Surinate®. In order to empty their bladders, men who have a urinary retention condition must rely on a 60-year-old product called a Foley catheter connected to a collection bag, or they must suffer through intermittent catheterization four to six times a day in order to relieve themselves.

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Surinate® is designed to eliminate the need for a urine-collection bag or the discomfort and inconvenience of intermittent catheterization. Surinate® is designed with a magnetic valve inside the catheter that allows the bladder to fill and then empty only on manual control by the patient. The patient uses an external magnet to open the valve in the Surinate® catheter to drain the bladder only when he needs to. Furthermore, the Surinate® valved catheter is designed to remain in the patient for up to 30 days. Thus, with Surinate® the patient himself has total control over his bladder-emptying process.

Urovalve, Inc. (www.urovalve.com) is a privately held company located in the Enterprise Development Center at New Jersey Institute of Technology (NJIT) in Newark, New Jersey. The company develops superior medical devices to address problems associated with urinary flow and control.

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