For Immediate Release:

# FDA Permits Marketing of Vesiflo's inFlow™ Device for Women

Non-Surgical Urinary Prosthesis with Breakthrough Technology Eliminates the Need for Urinary Catheters

REDMOND, WA, October 15, 2014 /BusinessWire/ -- Vesiflo, Inc., today announced that its Direct De Novo Petition for the inFlow™ Urinary Prosthesis has been granted by the U.S. Food and Drug Administration (FDA), allowing the inFlow to be freely marketed in the U.S.

The inFlow is a non-surgical device that provides a convenient and dignified alternative to urinary catheters. Its target population is women with atonic bladder, a medical condition where patients are unable to spontaneously urinate due to impaired detrusor contractility. Atonic means "no tone" – they cannot generate bladder pressure. Atonic bladder is believed to affect approximately 400,000 U.S. women with life-altering neurologic disease or injury such as stroke, multiple sclerosis, spinal cord injury, Parkinson's, spina bifida, diabetic neuropathies, etc. Atonic bladder is generally incurable and there are few clinical options. The vast majority of women with atonic bladder use urinary catheters for bladder drainage.

Although urinary catheters may be the most commonly used medical devices, with chronic use they cause serious problems, notably urinary tract infections (UTIs), encrustation and low quality of life. These problems are amplified for women with atonic bladder as they must now use urinary catheters on a life-long basis. The inFlow is intended to address catheter-related problems and, as a prosthetic device, to compensate for a specific anatomic deficiency. Since women with atonic bladder cannot generate bladder pressure, the inFlow *pumps* the urine out. It is an *active* device that replaces *passive* urinary catheters. The technology involved is considerable and is the result of extensive development over a 10-plus year period.

Vesiflo's CEO, Kevin M. Connolly, stated "We are excited to offer a product that can improve the lives of so many women with serious medical conditions. The inFlow allows almost normal use of a toilet. It eliminates the need to catheterize multiple times daily, eliminates tubes and drainage bags and restores personal dignity to a population in acute need."

**About the inFlow**

The inFlow is an intraurethral valve-pump in a silicone housing that comes in a variety of sizes. Device sizing and initial insertion is performed by a physician. Thereafter, a new device is inserted every 29 days, typically by a caregiver or spouse. Insertion is similar to that for a urinary catheter. Since the inserted device resides almost entirely in the urethra, only the user knows it's there. To void, the user sits on a toilet, holds a remote control over the lower pelvic area and presses a button. This magnetically activates the miniature internal pump, which drains the bladder at a normal flow rate. When the button is released, the valve is engaged, blocking further urine flow.

In its pivotal trial, the inFlow was as effective as the current standard of care, clean intermittent catheterization, in draining the bladder and improved quality of life by 54%, a difference that is statistically and clinically significant. In addition, the inFlow was shown to have the same or lower rate of urinary tract infection (UTI) as *intermittent* catheters, an unprecedented finding for an *indwelling* bladder drainage device.

The inFlow Urinary Prosthesis may now be freely marketed in the U.S. It is also for sale in Europe, including in Germany, where it is reimbursed by that nation's health system. Prior to broader market launch in the U.S., the inFlow will be available in certain centers of excellence.

**About Vesiflo**

Vesiflo, Inc. is dedicated to reinventing bladder drainage. Due to their acute need, our initial focus is on improving the lives of women with atonic bladder. We also plan to add related products through internal development and acquisition. Learn more at www.vesiflo.com.

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