# Tensys Medical receives US FDA 510(k) for TL-300, latest generation in continuous, non-invasive hemodynamic patient monitoring system

## Company To Present At 2013 OneMedForum

San Diego, California, January 3, 2013 – Tensys Medical, Inc., a leader in the development and commercialization of continuous, non-invasive hemodynamic patient monitoring systems has received 510(k) clearance from the US Food and Drug Administration (FDA) for the TL-300, the company's latest generation system. The TL-300 is a member of Tensys' established T-Line family, which has successfully been used by over 50,000 patients since commercial launch. The T-Line technology accurately and continuously captures a patient's beat-to-beat waveform and blood pressure in a completely non-invasive fashion, providing physicians with a stream of real-time hemodynamic data that is not possible using traditional non-invasive blood pressure (cuff) devices. Avoiding the blind-time associated with a deflated or inaccurate cuff can enhance hemodynamic monitoring, which has been definitively linked to improved clinical outcomes.

The TL-300 features a tablet supported monitor that allows touch screen control and displays a patient's key hemodynamic parameters. In addition to continuous beat-to-beat blood pressure and arterial waveform, the operator is readily able to view trend data for up to a 12-hour period. The tablet displays data coming from an integrated bracelet, sensor, and wrist frame placed over the patient's radial artery. The wrist frame is disposed at the end of the case and the bracelet and sensor are immediately available for the next patient. Today, the T-line family is used in a number of clinical environments including the operating room, intensive care unit (ICU), and electrophysiology lab.

"The TL-300 represents our continued commitment to delivering next generation, non-invasive, hemodynamic monitoring tools," commented Dr. Oliver Goedje, Tensys' Medical Director. "This new system will not only enhance our current product offering, but will serve as a platform as we add cardiac output and additional hemodynamic parameters in the near future."

Tensys will be providing additional details regarding the TL-300 launch and other company initiatives at the upcoming 2013 OneMedForum in San Francisco, California. Tensys management will be presenting on January 9<sup>th</sup> at 10:10AM (presentation room Franciscan). For additional details, please visit <a href="www.tensysmedical.com">www.tensysmedical.com</a> and/or contact Dr. Eric Daniels, Vice President, Marketing & Sales, Tensys Medical (edaniels@tensysmedical.com)

### **About Tensys**

Tensys Medical, Inc. is a leader in the development and commercialization of continuous, non-invasive, hemodynamic monitoring systems. Without a single needle stick, the company's FDA approved and CE-Marked T-line technology is used today in hospital operating rooms, ICUs and electrophysiology labs to provide a patient's real-time pulse pressure waveform and blood pressure. With the future addition of advanced hemodynamic parameters, Tensys is positioned to continue its leadership in the growing, non-invasive, hemodynamic marketplace.

## Cautionary Statement Regarding Forward-Looking Statements

This press release may include "forward-looking statements" intended to qualify for the safe harbor from liability established by the Private Securities Litigation Reform Act of 1995. These forward-looking statements generally can be identified by phrases such as "will," "near future," "positioned," "provide," or other words or phrases of similar import that are intended to identify forward-looking statements. Similarly, statements herein that describe Tensys Medical's business strategy, outlook, objectives, plans, intentions, or goals also are forward-looking statements. All such forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from those in forward-looking statements, including: the clinical and commercial potential and success of the company's TL-300 product and T-Line product line; general economic and business conditions; and other risks and important factors that could cause actual results to differ materially from the forward-looking statements. The forward-looking statements included in this press release are made only as of the date of this announcement, and Tensys Medical undertakes no obligation to update the forward-looking statements to reflect subsequent events or circumstances after the date on which they were made.

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