

Significant Results for InsuPatch™ in Clinical Study for FDA approval

**The analysis provides results from part of the clinical study for FDA approval conducted by the Company, which was completed earlier this year**

**Use of InsuPatch™ shows significant increase in blood insulin levels during the first hour after injection, compared to insulin levels without its use**

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**Israel, Petach Tikva, December 21, 2011 – InsuLine Medical** - a development, production and marketing company of technology and products designed to improve the effectiveness of insulin therapy – today announced that Primary Endpoint analysis of results from a clinical study for FDA approval of the InsuPatch™ product shows that the device significantly increases the relative insulin levels in the blood, during the first hour from injection.

**Ron Nagar, CEO, InsuLine:** "We are meeting our objectives and are very pleased with the trial results. They have proved once again the efficacy of the InsuPatch™ product. The success of this clinical study is an important milestone towards achieving our goal to bring a medical device with an added-value for patients, physicians, insurers and healthcare systems, all over the world. The analysis of the trial's results will support the Company's efforts to obtain FDA approval of the InsuPatch™. We are continuing the safety trials, which we hope to complete within the next few months. Immediately thereafter, we intend to file a request for FDA regulatory approval for the InsuPatch™ product".

This cross-over trial results show that, when using the InsuPatch™ product, there was an increase of 29.7% (median) in the relative insulin levels in the blood during the first hour after the injection, as compared to the blood insulin levels during the first hour after the injection without using the device. This improvement is higher than the 10% improvement which was required by the FDA trial protocol.

The statistical analysis of the trial results shows significance of  $p < 0.019$  for this primary end-point, while the significance required by the FDA protocol was  $p < 0.05$ . The clinical trial was completed by 55 diabetic patients, and the analysis of the results was evaluated for 51 participants who met all the clinical protocol requirements.

The second part of the trial, which tests the safety of InsuPatch™ product, began in early 2011 and is expected to end by April 2012. It includes over 100 participants in medical centers in Israel and one medical center in the USA.

After the completion of the second part of the trial and the analysis of its results, the Company intends to file a request for FDA approval of the InsuPatch™ product.