

## Press Information

### **Lombard Medical Technologies PLC** ("Lombard Medical" or "the Company")

#### **U.S. FDA Approval of Aorfix™**

**London, UK, 15 February 2013** – Lombard Medical Technologies PLC (AIM: LMT), the specialist medical technology company focused on innovative vascular products, today announces that Aorfix™ has been approved for commercial sale in the U.S. by the U.S. Food and Drug Administration ("FDA"). Aorfix™ is the Company's flexible stent graft for the endovascular repair of abdominal aortic aneurysms ("AAAs"). Data from the U.S. PYTHAGORAS trial of Aorfix™, has demonstrated that Aorfix™ can successfully treat a larger patient population than competing devices, including both standard and difficult to treat cases of AAAs.

The U.S. approval for Aorfix™ includes a label indication for the treatment of patients with angulations at the neck of the aneurysm from 0 to 90 degrees. Aorfix™ is now the only endovascular stent graft licensed in the U.S. for use in more challenging cases with neck angulations greater than 60 degrees. Independent market research suggests that the U.S. market for the repair of AAAs is worth over \$600 million per annum<sup>1</sup>, is forecast to grow at approximately 8%<sup>1</sup> per annum, and that up to 30% of all patients have some tortuosity either at the neck of the aneurysm or in the iliac arteries<sup>2</sup>. It is to this segment of patients that Aorfix™ is targeted with its uniquely flexible design. In Europe Aorfix™ is already licensed to treat neck angulations of up to 90 degrees.

The PYTHAGORAS trial of Aorfix™ is the largest prospective controlled study, to date, of stent grafting in patients with highly angled aortas. 218 patients at risk of aneurysm rupture were recruited in the trial and included 151 patients with neck angles greater than 60 degrees and 67 patients with neck angles less than 60 degrees. No aneurysms expanded in patients with neck angles less than 60 degrees and just 1.8% expanded in the patients with high neck angles, comparing favourably with the results of other devices in normal, less tortuous anatomy.

The approval of Aorfix™ triggers receipt of the c. £14.1m Second Tranche of the two tranche placing and subscription announced by the Company on 20 April 2011 (the "May 2011 Fundraising"). Funds from the Second Tranche will be used to launch Aorfix™ in the U.S. through the Company's own direct sales force. In addition to building the U.S. sales and marketing infrastructure, funds from the Second Tranche will also be used to expand production capacity to meet anticipated demand for the Aorfix™ stent graft, complete the planned extension of stent graft sizes and develop the next generation, lower profile delivery device.

Funds from the Second Tranche will also be used to redeem the full amount of the £3m Convertible Loan Notes issued to Invesco Asset Management Limited ("Invesco") to the extent that Invesco has not already converted, or indicated its willingness to convert, the Convertible Loan Notes. Additional funding will subsequently be sought to allow the Company to achieve its longer-term goals in the U.S.

U.S. approval of Aorfix™ also triggers the Company's ability to draw down \$2.5m from the \$5.0m loan facility granted by its exclusive distribution partner in Japan, Medico's Hirata Inc. Medico's Hirata is a leading supplier and developer of medical device products in Japan, with the sales infrastructure to maximise the potential of Aorfix™ in this important market. Lombard Medical continues to work with its partner to achieve Aorfix™ approval in Japan, which it anticipates will be in 2014.

In May 2012 the Company announced a strategic partnership with Machine Solutions Inc. (MSI), a global supplier of process and testing solutions for the medical device industry. This partnership formed part of the Company's wider plan to develop improved manufacturing processes and efficiencies for Aorfix™. In utilising technology developed in collaboration with Machine Solutions, the Company is confident of meeting product demand and capacity requirements following the launch of Aorfix™ in the U.S.

#### **CEO of Lombard Medical Technologies, Simon Hubbert, commented:**

*"FDA approval of Aorfix™ is a major milestone for the Company and sets the stage for the next chapter in the Company's growth. I would like to thank all of our employees, investigators and clinical advisors for their support and hard work, without which development and approval of Aorfix™ would not have been possible. Aorfix™ is now the only stent graft approved in the U.S. to treat AAAs with neck angulations up to 90 degrees, a key advantage over other currently available stent grafts. We look forward to launching Aorfix™*

*in the U.S. through our own sales force and are confident of securing a meaningful share of this growing market."*

**Dr Mark Fillinger of Dartmouth Hitchcock Medical Centre, New Hampshire (principal investigator for the Aorfix™ trial), commented:**

*"Having seen the benefits of using Aorfix™ in patients first hand, I am very pleased that the device is now available to treat patients in the U.S. Aorfix™ allows a minimally invasive repair to be performed in AAAs with complicated highly-angulated aortic necks. This addresses a clear unmet medical need, as there are no other devices in the U.S. approved for use in 60-90 degree aortic necks. These patients would otherwise require open surgery, which is more invasive and higher risk, yet many of these patients are poor candidates for open repair."*

**-Ends-**

**For further information:**

**Lombard Medical Technologies PLC**

Simon Hubbert, Chief Executive Officer  
Ian Ardill, Chief Financial Officer

Tel: 01235 750 800

**Canaccord Genuity Limited**

Lucy Tilley / Rob Collins / Tim Redfern

Tel: 020 7523 8000

**FTI Consulting**

Simon Conway / Susan Stuart / Victoria Foster Mitchell

Tel: 020 7831 3113

**About Lombard Medical**

Lombard Medical Technologies PLC (AIM: LMT), is a medical device company focused on device solutions for the \$1.2 billion dollar per annum abdominal aortic aneurysm (AAA) repair market. AAAs are a balloon-like enlargement of the aorta which, if left untreated, may rupture and cause death. Approximately 4.5 million people are living with AAAs in the developed world and each year 600,000 new cases are diagnosed. The market for endovascular stent grafts for this application is expected to grow to \$1.6 billion by 2015. The Company's lead product, Aorfix™, is an endovascular stent graft which has been specifically designed to solve the problems that exist in treating complex tortuous anatomy which is often present in advanced AAA disease. Aorfix™ is currently being commercialised in the EU, and has been approved by the FDA in the U.S., the first AAA stent graft not of U.S. origin to gain FDA approval.

The Company is headquartered in Oxfordshire, with operations in Ayrshire and Phoenix, USA.

Further background on the Company can be found at [www.lombardmedical.com](http://www.lombardmedical.com).

**About Medico's Hirata**

Founded in 1918 and headquartered in Osaka, Medico's Hirata Inc. is a leading supplier and developer of medical device products for the Japanese healthcare industry. With more than 100 devices approved, the Company has built up extensive industry experience and a thorough understanding of the regulatory landscape in Japan. In 2006 the Company received regulatory approval to launch aortic stent grafts for the treatment of abdominal aortic aneurysms ("AAAs"), complementing its broad portfolio of minimally invasive, innovative devices in the field of vascular intervention.

Further background on the Company can be found at <http://www.medicos-hirata.co.jp/english/>

**May 2011 Fundraising**

In May 2011, the Company completed a two tranche fundraising, incorporating a placing, subscription and offer, of £27.2m before expenses. The first tranche ("First Tranche") of £13.0m was supported by certain existing shareholders and two new shareholders at the time, Abingworth LLP and MVM Life Science Partners LLP. These same shareholders committed to subscribing for further shares in the Company through a £14.2m second tranche of fundraising ("Second Tranche") under pre-agreed terms and subject to certain milestones and conditions being achieved (or waived by certain of the investors). As announced on 20 December 2012, the original Long Stop Date of the Second Tranche was extended from 31 December 2012

to 30 June 2013 and in addition to certain existing shareholders, the Second Tranche will now be supported by LSP Life Sciences Fund N.V. ("LSP") replacing MVM Life Science Partners LLP ("MVM"), who decided to assign their rights to subscribe for new ordinary shares in the Second Tranche.

### **Convertible Loan Notes**

In March 2012, the Company issued £3m Convertible Loan Notes to Invesco Asset Management Limited. The interest rate on the Convertible Loan Notes is 8.0 per cent. per annum compounded annually and is payable by the Company on 30 June 2012, 31 December 2012, 30 June 2013 and 1 September 2013. The Convertible Loan Notes Holder is, at any time between 1 July 2013 and 1 September 2013, entitled to convert the Convertible Loan Notes plus any accrued but unpaid interest into new Ordinary Shares at a conversion price of 140 pence per Ordinary Share.

### **References**

1. U.S. Market for Peripheral Vascular Devices, iData Research Inc., 2010
2. Eurostar Study results (Frequency, predictive factors, and consequences of stent-graft kink following endovascular AAA repair. Fransen GA, Desgranges P, Laheij RJ, Harris PL, Becquemin JP; EUROSTAR Collaborators . Published in J Endovasc Ther. 2003 Oct;10(5):913-8.)