

QualiMed Innovative Medizinprodukte GmbH, a Q3 Medical Devices Ltd, subsidiary:

UNITY Balloon Expandable Bioresorbable Hybrid Biliary/Peripheral Vascular Stent Implanted for the 1st Time in Southeast Asia



Southeast Asia, Feb 11, 2016 /PR/ - The UNITY Balloon Expandable Bioresorbable Hybrid Biliary/ Peripheral Vascular Stent was implanted successfully in Southeast Asia. A young man in his 20s was treated with a UNITY Biliary Bioresorable Stent for recurrent common bile duct obstruction post removal of a traditional plastic stent. The traditional plastic stent had to be removed because it had occluded causing a blockage in the bile duct. Stents which are small mesh like tubes used to hold open ducts or arteries are made of various materials like metals and plastics. Both metal and plastic stents are associated with problems like tissue ingrowth, blockage, migration, fracturing, and other associated mechanical failures. With plastic biliary stents being used an estimated 1 Million times annually and routinely having to be removed within months after their placement do to blockage their remains a significant opportunity to reduce patient complications and total procedure cost through the use of a device that does not need to be removed and will disappear over time,"Bioresorbe." These repeat procedures to address complications or effect the removal of the traditional stents increase patient risk and add tremendous cost burden to the patients and the global insurance providers. As an example "It is estimated that the total procedure cost for the placement or removal of a device for endoscopic biliary indications is approximately \$3,000 or more. A device that could eliminate the removal procedure and disappear may significantly reduce the cost and complications associated with such surgeries" stated Eric K Mangiardi, CEO of Q3 Medical.

The novel **UNITY Balloon Expandable Bioresorbable Hybrid Biliary/Peripheral Vascular Stent** combines a bioresorbable magnesium center like your bone and a bioresorable polymer outer like your muscle. When combining the two materials together the device acts more like a metallic stent and will eventually be used in hundreds of thousands of procedures annually.



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The stent is made of well-known biodegradable polymers used in traditional suture materials and a proprietary magnesium based alloy. Magnesium as an example can be found in the sparkling water you drink. After the completion of the first in man study the company will initiate a similar trial for peripheral indications and expects to conduct its trial for coronary procedures in the second half of 2016. The UNITY Biliary approval is forecasted for the 2nd half of 2016, followed by UNITY Peripheral, and UNITY Coronary devices respectively.

"The company is preparing for all three product submissions and clinical studies as it focuses on its strategy to become the leading bioresorbable company globally" stated Martina Schmitt, Managing Director at QualiMed.

The device is for investigational purposes only and is not CE or FDA approved at this time.

Speaking on behalf of Q3 Medical and QualiMed Eric K Mangiardi, CEO of Q3 Medical, commented: "This is a significant milestone for the company as we continue to explore developments in the area of biodegradable implants that will improve efficacy and eliminate cost for the patients, care givers, and insurance providers. Qualimed is focused on continuing its development of bioresorbable technology for the biliary, peripheral, and coronary interventions including covered stent technology."

#### **About QualiMed**

QualiMed, a wholly owned subsidiary of Q3 Medical, was founded in 1997 in Winsen, Germany near Hamburg, where it develops, manufactures and sells implantable medical devices in the Cardiology, Peripheral Vascular, and Non Vascular areas. The innovations are focused in the areas of Biodegradable Products, Drug Device Combination Technologies, Catheter and Mechanical implant areas. Originally founded as an OEM, the company's products are now sold in over 50 countries worldwide through its OEM, Private Label, and Own Brand Networks. The company and its development partners have obtained CE and FDA approvals for more than 70 different products including 3 different drug eluting stents.

#### **About Q3 Medical Devices Limited**

Q3 Medical Devices Limited is an Irish based holding company with multiple operations in Germany and strong partnerships throughout Asia through its growing investor base, including China Pioneer Pharma Holdings Limited listed on the Hong Kong Exchange (1345). The holding and its companies are focused on the development, manufacturing and distribution of minimally invasive devices for the treatment of patients with cardiology, peripheral vascular and non-vascular diseases.

Q3 Medical Devices Limited was formed by a global group of entrepreneurs, manufactures, distributors, industry doctors and investors, focused on the development and acquisition of medical device businesses with annual revenues between 1-10 Million. The acquisitions are targeted in areas that expand the groups manufacturing base and capabilities, resulting in the growth of its distribution channels and accelerating its products offering, focusing on the minimally invasive treatment of patients with cardiology, peripheral vascular and non-vascular diseases.

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#### **Forward Looking Statements**

This announcement includes "forward-looking statements" which incorporates all statements other than statements of historical facts, including, without limitation, those regarding the Group's financial position, business strategy, plans and objectives of management for future operations (including development plans and objectives relating to the Group's products and services), and any statements preceded by, followed by or that include forward-looking terminology such as the words "targets", "believes", "estimates", "expects", "aims", "intends", "will", "can", "may", "anticipates", "would", "should", "could" or similar expressions or the negative thereof. Such forward-looking statements involve known and unknown risks, uncertainties and other important factors beyond the Group's control that could cause the actual results, performance or achievements of the Group to be materially different from future results, performance or achievements expressed or implied by such forward-looking statements. Such forward-looking statements are based on numerous assumptions regarding the Group's present and future business strategies and the environment in which the Group will operate in the future. Among the important factors that could cause the Group's actual results, performance or achievements to differ materially from those in forward-looking statements include those relating to QualiMed's funding requirements, regulatory approvals, clinical trials, reliance on third parties, intellectual property, key personnel and other factors. These forward-looking statements are valid at the date of this announcement. The Group expressly disclaims any obligation or undertaking to disseminate any updates or revisions to any forward-looking statements contained in this announcement to reflect any change in the Group's expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based. As a result of these factors, readers are cautioned not to rely on any forward-looking statement.

### For more enquiries and/or photos of event, please contact



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#### Patient left in 24 hours post placement and so far no issues at 10 plus days.



**Photo 1:** Current clogged plastic stent that needed to be removed.



Photo 4: Stent passing through the Papilla.



**Photo 2:** Recanulation of the duct. (You can see the bile start to flow)



**Photo 5:** Stent visible under floroscopy. (big markers are balloon markers)



**Photo 3:** Loading of stent over 0.035 wire to pass through the endoscope. (Notice the placement of the orange introducer cap)



**Photo 6:** Balloon dilation in duct under floroscopy with contrast in balloon.

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**Photo 7:** Balloon inflation photo outside of duct with direct view of Papilla and proximal end of the stent.

**Photo 8:** Stent open in Papilla drainage possible. Look through the stent at the posterior wall.

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