

## Italy's Plan 1 Health Uses Solvay's Eviva® PSU in Implantable Drug Infusion System

Thermoplastic Biomaterial Delivers Light Weight and MRI Compatibility in Healthport® Catheter Port

**ALPHARETTA, Ga., June 13, 2013** – Implantable catheter ports from Plan 1 Health S.r.I, Amaro, Italy, a leading designer and manufacturer of implantable dental and infusion systems, are made of Eviva<sup>®</sup> polysulfone (PSU) resin from Solvay Specialty Polymers for biocompatibility, dimensional stability, and MRI compatibility. Eviva<sup>®</sup> PSU resin is part of Solvay's Solviva<sup>®</sup> Biomaterials line offered for use in implantable medical devices.

Plan 1 Health's Healthport<sup>®</sup> catheter port system is versatile and highly reliable for delivery of drugs, antibiotics, and nutrient therapy solutions. The Healthport<sup>®</sup> Plastics Low Profile (PLP) model is lightweight and cost-effective, and it features a low-profile PSU housing that is suitable for all patients. A titanium inner chamber avoids damages induced by the needle tip and avoids interactions between Eviva<sup>®</sup> PSU and the drug. A large self-sealing septum facilitates location during skin palpation and reduces the risk of puncture concentration. A transparent polyurethane connector allows a rapid, safe, and reversible connection of the catheter.

The catheter port is a multi-piece assembly consisting of an injection molded housing and ring component, both made of Eviva® PSU, and a titanium inner chamber. The PLP model is lighter and more cost-effective than previous all-titanium versions which require more expensive manufacturing techniques, according to Alessandro Rainis, product manager for Plan 1 Health. The titanium chamber is fixed between the two plastic components that are ultrasonically welded together.

Eviva® PSU is a transparent polymer that offers toughness and strong biocompatibility. The material maintains its dimensional tolerance right out of the mold and requires no machining. It is a rigid thermoplastic that doesn't absorb fluids and is artifact-free for effective MRI imaging.

"We've been very pleased to work with Plan 1 Health as they develop advanced approaches for implantable infusion systems," said Shawn Shorrock, global healthcare market manager for Solvay Specialty Polymers. "The ongoing acceptance of Eviva® PSU has validated our approach to the implantable infusion market and we're encouraged by the momentum we've generated."

The manufacturing site for Eviva<sup>®</sup> PSU and other Solviva<sup>®</sup> Biomaterials in Alpharetta, Ga., is ISO 13485 registered and the relevant aspects of current Good Manufacturing Practices are also applied. Solvay's Solviva<sup>®</sup> Biomaterial manufacturing processes are carefully validated and enhanced controls provide product traceability. In addition, all materials are tested in an ISO 17025 accredited lab. Based on biocompatibility testing, Eviva<sup>®</sup> PSU demonstrates no evidence of cytotoxicity, sensitization, irritation or acute systemic toxicity.

The catheter ports – sold to medical device distributors in Europe, Asia, and India – have earned the CE (Conformité Européenne) mark which demonstrates compliance with numerous EC directives, enabling the product to be sold throughout the Euro region. Plan 1 Health is also exploring the option of seeking 510(k) clearance from the U.S. Food & Drug Administration (FDA) and entering the U.S. market.

In addition to Eviva<sup>®</sup> PSU, Solvay's Solviva<sup>®</sup> Biomaterials line includes Zeniva<sup>®</sup> polyetheretherketone (PEEK), which boasts a modulus very close to that of bone plus excellent toughness, biocompatibility and fatigue

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resistance; Proniva<sup>®</sup> self-reinforced polyphenylene (SRP), one of the world's stiffest and strongest unreinforced thermoplastics, which offers exceptional biocompatibility and hardness; and Veriva<sup>®</sup> polyphenylsulfone (PPSU), which provides unsurpassed toughness combined with transparency and excellent biocompatibility.

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## **About Plan 1 Health**

Plan 1 Health, based in Amaro, Italy, is a leading manufacturer of implantable dental and drug infusion systems. The company has dedicated resources and wide-ranging experience in the design and production of implantable devices. Plan 1 Health works with the customer from concept idea to project development, engineering, certification, and product release. The company understands the clinical needs "on the field" and converts them into reliable industrial products ready for the market. Manufacturing meets all the necessary quality requirements including ISO 13485 and MDD 93/42. For more information, visit www.p1h.it.

## **About Solvay Specialty Polymers**

Solvay Specialty Polymers is a leading global supplier of high-performance thermoplastics for implantable and non-implantable medical devices. The company has expanded its focus on the healthcare industry to meet the growing needs of its global customers. Solvay is building on its 20-year history as a key material supplier in the healthcare field, devoting considerable new resources to help customers be more efficient and cut costs. Metal-to-plastic replacement remains a key focus for manufacturers, but increased cost pressures pose a new challenge as the market continues to grow at a double-digit pace. Solvay also continues to devote considerable research and development activities to polymer technology and commercialization of new and unique material options for medical OEMs and processors.

Solvay Specialty Polymers manufactures over 1500 products across 35 brands of high-performance polymers – fluoropolymers, fluoroelastomers, fluorinated fluids, semi-aromatic polyamides, sulfone polymers, aromatic ultra polymers, high-barrier polymers and cross-linked high-performance compounds – for use in Aerospace, Alternative Energy, Automotive, Healthcare, Membranes, Oil and Gas, Packaging, Plumbing, Semiconductors, Wire and Cable, and other industries. Learn more at www.solvay.com.

As an international chemical group, <u>SOLVAY</u> assists industries in finding and implementing ever more responsible and valuecreating solutions. The Group is firmly committed to sustainable development and focused on innovation and operational excellence. Solvay serves diversified markets, generating 90% of its turnover in activities where it is one of the top three worldwide. The group is headquartered in Brussels, employs about 29,000 people in 55 countries and generated 12.4 billion euros in net sales in 2012. Solvay SA <u>SOLB.BE</u>) is listed on <u>NYSE Euronext</u> in Brussels and Paris (Bloomberg: <u>SOLB.BB</u> - Reuters: <u>SOLBt.BR</u>).

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