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**ADVANCED POLYMERS**

**For Immediate Release**

## **Advanced Vertebral Solutions Wins FDA Clearance for New Spinal Implant Made of Solvay's Zeniva® PEEK**

*Versatile Biomaterial Brings Exceptional Performance to Spinal Fusion Application*

**ALPHARETTA, Ga., October 5, 2010** – Advanced Vertebral Solutions (AVS), Doylestown, Pa., a leading supplier of minimally invasive spinal implants and delivery systems, has received 510(k) clearance from the U.S. Food & Drug Administration (FDA) for its new Steerable TLIF spinal fusion implant made of Zeniva® polyetheretherketone (PEEK) resin from Solvay Advanced Polymers, LLC. Zeniva® PEEK – part of Solvay's Solviva® line of biomaterials – has a modulus very close to that of bone plus excellent toughness and fatigue resistance. The FDA clearance was based in part on Solvay's well-developed master access file for Zeniva® PEEK.

The EXPRESS IBFD™ TLIF implant, made from 30- and 40-mm-diameter Zeniva® PEEK rod stock, is an implant for interbody fusion of the anterior column of the spine. These implants are hollow so that bone can grow through the device, fusing the adjacent bony surfaces of the vertebrae. AVS has developed a unique “active steering” technology that minimizes instrument exchanges and simplifies the minimally invasive surgical technique, thereby enabling its rapid adoption among spine surgeons.

“Zeniva® PEEK provides the exceptional properties that are required of a high-

precision implant in this critical application,” said Mike Dugery, president of Advanced Vertebral Solutions. “We foresee our active steering platform becoming the benchmark for TLIF implant delivery and we are extremely happy with the technical support Solvay has provided.”

Zeniva® PEEK is a comparable or better-performing alternative to metals such as titanium for these intervertebral implantable devices. The material offers many important benefits including biocompatibility, chemical inertness, and a modulus of elasticity that is close to that of bone. Based on biocompatibility testing, Zeniva® PEEK demonstrates no evidence of cytotoxicity, sensitization, irritation, or acute systemic toxicity. It also boasts high strength and stiffness and has radiolucent properties which permit x-ray procedures. Advanced Vertebral Solutions uses Zeniva® PEEK rod stock and performs high-precision machining to produce a full range of sizes and configurations.

“We’re excited about the commercial adoption of Zeniva® PEEK for this unique spinal fusion implant,” said Shawn Shorrock, global healthcare market manager for Solvay Advanced Polymers. “We’ve made significant investments and performed all applicable required testing to ensure that our Zeniva® PEEK meets or exceeds the critical regulatory performance standards set by the FDA for this application.”

Zeniva® PEEK and the entire line of Solviva® Biomaterials are manufactured in compliance with the relevant aspects of ISO 13485 and under the relevant aspects of current Good Manufacturing Practices. Solvay’s biomaterial manufacturing processes are carefully validated and enhanced controls provide product traceability. In addition, all materials are tested in an accredited lab that is ISO 17025 compliant.

Solvay is currently in active product trials with several medical device manufacturers, not only with Zeniva® PEEK, but using the broad range of Solviva®

## Biomaterials.

In addition to Zeniva® PEEK, Solvay's Solviva® Biomaterials line includes Proniva® self-reinforced polyphenylene (SRP), one of the world's stiffest and strongest unreinforced thermoplastic that offers exceptional chemical resistance and hardness; Veriva® polyphenylsulfone (PPSU), which provides unsurpassed toughness combined with transparency and excellent chemical resistance; and Eviva® polysulfone (PSU), which offers practical toughness in a strong, transparent polymer. These sterilizable products are available in resin for injection molding or extrusion.

### **About Advanced Vertebral Solutions**

Advanced Vertebral Solutions (AVS), based in Doylestown, Pa., is a privately-held spinal company focused on minimally invasive spinal fusion surgery. The company's EXPRESS IBFD™ implant and instrumentation system incorporates its proprietary "active steering" technology that enables the spinal fusion implant to be steered into place by the surgeon rapidly and precisely and without the need for multiple instruments or instrument exchanges. AVS has developed a complete line of Zeniva® PEEK and titanium implants that incorporate the "active steering" technology. For more information, visit [www.steerableTLIF.com](http://www.steerableTLIF.com).

### **About Solvay Advanced Polymers**

Solvay Advanced Polymers, LLC produces more plastics with more performance than any other company in the world. This gives design engineers worldwide more ways to solve top design challenges in automotive, medical, electronics, aerospace and other demanding industries. Learn more at [www.solvayadvancedpolymers.com](http://www.solvayadvancedpolymers.com).

Solvay is an international industrial Group active in Chemistry. It offers a broad range of products and solutions that contribute to improving quality of life. The Group is headquartered in Brussels and employs 17,000 people in over 40 countries. In 2009, its consolidated sales amounted to EUR 8.5 billion. Solvay is listed on the NYSE Euronext stock exchange in Brussels (NYSE Euronext: [SOLB.BE](http://www.nyse.com/quote/SOLB:BE) - Bloomberg: [SOLB.BB](http://www.bloomberg.com/quote/SOLB:BB) - Reuters: [SOLBt.BR](http://www.reuters.com/quote/SOLBt:BR)). Details are available at [www.solvay.com](http://www.solvay.com).

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