

## **Carbylan BioSurgery Announces Positive Clinical Trial Results for Hydros-TA in Patients with Pain from Knee Osteoarthritis**

**Palo Alto, CA – July 25, 2011** - [Carbylan BioSurgery, Inc.](#) today announced positive results in its double-blinded, multi-center COR1.0 clinical trial which evaluated the safety and effectiveness of [Hydros-TA Joint Therapy](#) (Hydros-TA) and [Hydros](#) as compared to Synvisc-One® in patients with osteoarthritis of the knee. The study data indicated the potential for Hydros-TA to provide superior pain relief and improved function when compared to Synvisc-One®. Hydros-TA is a single-injection next generation viscosupplement/steroid combination product, and Hydros is the viscosupplement component alone.

"We are extremely pleased with the COR1.0 study outcome and are looking forward to confirming these results in an upcoming large, multi-center trial in the U.S.", said George Daniloff, M.D./Ph.D, President and CEO of Carbylan BioSurgery.

The [COR1.0 clinical trial](#) was conducted at eight clinical sites in Canada, Belgium, and The Netherlands. The trial was designed to evaluate the safety and effectiveness trends of a single injection of Hydros-TA or Hydros compared to Synvisc-One®, the market leading viscosupplement. A total of 98 patients were treated and followed for six months post injection.

"Hydros-TA performed very well compared to Synvisc-One®," said Marcee Maroney, Vice President of Clinical Affairs and Marketing at Carbylan. "Hydros-TA demonstrated the potential to provide greater pain relief with faster onset than Synvisc-One®. Hydros-TA also appeared to be associated with a lower rate of product related adverse events, including post-injection pain."

In addition to the positive results observed in the pain and function scores, Hydros-TA appeared to provide a higher response rate (percentage of patients with a clinically meaningful improvement) when compared to Synvisc-One®. Market research has shown that a predictable and consistent response to intra-articular therapy is considered by physicians to be one of the most important parameters with respect to product preference.

"Hydros-TA is an exciting new development in the treatment of osteoarthritic pain. It combines two well known treatment therapies, viscosupplementation and intra-articular corticosteroid, and provides the patient with a single, fast-acting, long-lasting therapy which appears to be very effective," said Robert Petrella, M.D. principal investigator for the COR1.0 trial and Beryl & Richard Ivey Research Chair at the Lawson Health Research Institute in Ontario, Canada.

Carbylan plans to begin evaluating Hydros-TA in a large, multi-center trial in the U.S. in 2012.

### **About Hydros-TA and Hydros Joint Therapies**

[Hydros Joint Therapy](#) is an intra-articular viscosupplement injection therapy comprised of bacterially derived hyaluronic acid (HA) which is chemically modified to form biodegradable hydrogel beads. Hydros was designed to provide sustained pain relief for up to six months with a single injection. [Hydros-TA Joint Therapy](#) is a novel viscosupplement with a dual mode of action, which traps a low dose of triamcinolone acetonide (corticosteroid) inside the Hydros hydrogel beads. Hydros-TA was designed to provide faster acting, longer lasting pain relief than either viscosupplements or steroids alone. Hydros-TA allows for sustained local delivery of a low dose steroid reducing the risk of systemic steroid exposure and the potential cartilage degradation associated with steroid injections in the knee. There is currently no similar viscosupplement/steroid combination product available to treat the pain associated with osteoarthritis.

### **About Osteoarthritis and Viscosupplementation**

[Osteoarthritis](#) (OA), also known as degenerative arthritis or degenerative joint disease, is a group of mechanical abnormalities involving degradation of joints, usually signaled by symptoms of pain, stiffness, and decreased function. OA affects nearly 27 million Americans. It is also the most common cause of disability in the United States. Common therapies to treat osteoarthritis include physical therapy, non-steroidal anti-inflammatories, and intra-articular injections of steroids and viscosupplements. The U.S. market for intra-articular viscosupplements was approximately \$700 million USD in 2010 and only approximately 7-10% of potentially eligible patients were treated.

### **About Carbylan BioSurgery, Inc.**

Carbylan ([www.carbylan.com](http://www.carbylan.com)) was founded in 2005 to develop and market medical devices and device/drug combination products based on novel chemically engineered polymer systems incorporating hyaluronic acid, a well-known polysaccharide widely present in the human body. Its initial market focus is therapeutic medical devices and combination products to treat the pain associated with osteoarthritis. Carbylan biopolymers are novel biomaterials which when combined with pharmaceutical agents enable the development of unique medical products.

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