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BIORTHEX RECEIVES APPROVAL FROM FDA TO BEGIN CLINICAL STUDY ON ACTIPORE™ PLFx

Montreal, CANADA, July 2nd, 2003 – Biorthex Inc., a medical device company specializing in spine, is pleased to announce the conditional approval from the American Food and Drug Administration (FDA) for the initiation of a U.S. clinical study for its *Actipore™ PLFx* Posterior Lumbar Fusion device. This conditional approval grants Biorthex the right to immediately initiate its study in the U.S. while adjusting its protocol to suit FDA requirements.

The *Actipore™ PLFx* device is indicated for patients suffering from back pain associated with degenerative disc disease (DDD) in the lumbar spine. This study, to be initiated this summer, will be a randomised, prospective, multi-center clinical trial designed to determine the safety and efficacy of the *Actipore™ PLFx* interbody fusion device.

The objective of the study is to compare radiographic evidence of fusion, pain/function and safety evaluation of 200 patients treated with the *Actipore™ PLFx* interbody fusion devices combined with a posterior fixation system to the same outcome of a group of patients (200) treated with bone graft (allograft) with the same posterior fixation system.

Medtronic Sofamor Danek, the largest company in the spine industry, has agreed to participate in this study by providing logistical support as well as their *CD HORIZON® Spinal System*, a posterior fixation system to be implanted in every patient participating in the study.

This study is intended to determine whether *Actipore™ PLFx* devices are as safe and effective as allograft material in support of a Premarket Approval (PMA) application to be filed with the American FDA in the aim of commercializing the device in the U.S. in 2007.

More than a dozen centers in the United-States are under consideration for participating in the study.

Benoit Sicotte, President and CEO of Biorthex stated, "Biorthex with its innovative biomaterial, has completed another important milestone. Obtaining approval from the FDA is the reward for extensive pre-clinical studies which all pointed in the same direction: the safety and efficacy of *Actipore™*. We are extremely happy to have received FDA approval to initiate a U.S. clinical study, as accessing the North American market is a priority for Biorthex. The U.S. spinal fusion implant and allograft market is estimated at approximately US\$670 million per year and is expected to reach US\$1.3 billion by 2008. It is without a doubt, the segment in orthopaedics which has the highest growth rate and we intend to benefit from it."

Through Actipore™, Biorthex holds a unique ultra porous biologically and biomechanically compatible material, with a porous structure consisting of interconnected passageways, which permits long term bone cell integration and survival throughout the devices. This exclusive technology platform has similar mechanical properties to bone, resulting in load sharing, rapid tissue ingrowth and eliminating the requirement for additional bone graft material, thus reducing the time of surgery, the risk of complications and preventing graft site morbidity.

Biorthex Inc. is a medical device company that designs, develops, manufactures and markets innovative products for the surgical treatment of spinal disorders.

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