



## Press Information

For Immediate release

19 September 2006

### **ApaTech announces initiation of landmark study. APPRAISE to compare Actifuse™ directly with Infuse™**

ApaTech a global leader in synthetic bone graft technologies, today announces the launch of a ground breaking multicentre international study to directly compare Actifuse™ Synthetic Bone Graft, its unique silicate substituted bone grafting material with Infuse® Bone Graft, the leading recombinant human Bone Morphogenetic Protein (rhBMP).

APPRAISE (**A** Prospective **PLF** Randomised **Actifuse** **InfuSe** **E**valuation) will compare Actifuse granules, mixed with operative site blood only, to Infuse, used according to its manufacturer's recommendations, in instrumented Posterolateral Lumbar spinal Fusion (PLF) procedures. The study will be conducted internationally to the highest GCP standards in leading independent spine centres and will evaluate whether there is any statistically significant difference between the two products. Patient data will be available for review 12 and 24 months post-operatively.

Commenting on today's announcement, Simon Cartmell, CEO of ApaTech, said 'Actifuse has been implanted successfully in over 4000 cases. Feedback from surgeons around the world indicates that they observe rapid and significant fusion mass develop with Actifuse. We have seen early, good quality fusion in PLF with Actifuse, comparable to that achieved with rhBMPs. In today's cost conscious environment, when surgeons are looking to provide the best treatment while remaining fiscally responsible, it is important to confirm these case reports in a prospective, well-controlled study. We are excited about the possible outcomes and will keep the surgeon community abreast of the data as it emerges to aid them in making their choice of bone graft material'.

Dr. Jim Cassidy, VP Global Development at ApaTech, underlined the rationale for the study thus: 'We have clearly demonstrated that the silicate substitution in Actifuse accelerates all stages of the natural osteogenic process, unlike rhBMP products. Infuse and other rhBMPs provide a supra-physiological dose of only one component of the bone formation cascade and 'kick start' it at that point. This can deliver good results, but has raised concerns about the appropriateness of this type of intervention. Actifuse may represent a more natural approach to deliver more bone in less time. We are confident APPRAISE will demonstrate that there is no difference in clinical outcomes between the two products.'

Dr. Tushar Patel of Commonwealth Orthopaedics and Rehabilitation, Herndon, Virginia, USA stated 'Actifuse has proven to be a very effective bone graft material in my practice and the results of APPRAISE could be far reaching. I am looking forward to the results of this well designed, large scale international study to guide treatment of spinal disorders in what will be, in the very near future, an increasingly older population.'

**Ends**

## Further Information:

### ApaTech

Simon Cartmell, CEO  
[Simon.cartmell@apatech.com](mailto:Simon.cartmell@apatech.com)

[www.apatech.com](http://www.apatech.com)

020 8731 4640

### Waughton

Robin Hepburn  
[rhepburn@waughton.com](mailto:rhepburn@waughton.com)

[www.waughton.com](http://www.waughton.com)

020 7796 9999

## Notes to Editors:

### About ApaTech

ApaTech's technology is based on extensive research to design the optimum material and structure for safe, effective bone grafting.

ApaTech's research has created Actifuse, a product with unique silicate substituted calcium phosphate chemistry, produced as a scaffold with consistent interconnected macro- and microporosity. As a result of its unique properties Actifuse outperforms traditional hydroxyapatite and  $\beta$ -tricalcium phosphate scaffolds in terms of the rate of new bone formation, the quantity of bone developed, and its quality. Actifuse also provides surgeons with a safe alternative to autograft without the complications associated with donor site surgery. Over 25 scientific publications are available to support the superior performance of Actifuse and to explain its mechanism of action.

ApaTech was spun out of Queen Mary University of London in 2001 and funded by 3i, who have participated in all funding rounds and are the Company's largest shareholder. The pivotal Series B round in April 2004 was lead by UK venture capital firm, MTI Partners.

ApaTech is based in Elstree, UK and Foxborough, MA, USA. The Company sells in the US, UK and 15 other countries around the world. More details can be found at the website, [www.apatech.com](http://www.apatech.com)

### About Posterolateral Lumbar Spinal Fusion

Spinal fusion is used to treat a range of diagnoses including degenerative disc disease, spondylolisthesis, scoliosis, or for traumatic injury. The objective of spine fusion is to improve patients' back pain by eliminating motion at the damaged level of the spine. In an instrumented posterolateral lumbar spine fusion, surgery is performed from the back with metal screws being placed through the pedicle bones of the spinal column. These screws are attached to rods or plates to rigidly fix the spinal motion segments. To ensure long-term immobilization, bone graft material is placed along the sides of the rear of the spine in order to stimulate bone growth across the motion segment, thereby "fusing" the spine.

### About APPRAISE

The objective of the APPRAISE Study is to assess bony fusion in patients requiring one or two level instrumented posterolateral lumbar spine fusion. Clinical outcomes will be assessed using standard measures. Evaluations will be done before surgery, prior to hospital discharge, then at four months, one year, and two years following surgery. These will include radiographs and CT scans at appropriate intervals.

Actifuse is a new class of synthetic bone graft. Its unique silicate substituted chemical chemistry accelerates the bone healing cascade. This silicate substitution creates a material

that promotes rapid formation of bone and increases the volume of bone formed in the graft/host bone composite structure. Macro- and micro-porosity allows newly forming bone and capillary blood vessels to grow throughout the network of interconnecting pores. Unlike many synthetic bone graft products, Actifuse retains its three-dimensional structure until bone repair is achieved.

INFUSE® Bone Graft is recombinant human bone morphogenetic protein-2 (rhBMP-2). Bone morphogenetic protein is a manufactured version of a natural protein found in small quantities in the body. The purpose of the protein is to stimulate bone formation.