bioengineering technological services

FOR IMMEDIATE RELEASE

NEW TELESCOPIC SYSTEM FOR TREATMENT OF OI CLEARED BY US-FDA

February 10, 2003 – Montreal, Canada. Pega Medical announces that after three years of successful clinical use in Canada, South America and Eastern Europe, it has been granted 510(k) clearance from the U.S. Food and Drug Administration (FDA) to market its Fassier-Duval Telescopic IM Nail System. This novel device is used for the surgical treatment of bone deformities and fractures in patients suffering from Osteogenesis Imperfecta (OI) and limb length discrepancy (LLD).

About Osteogenesis Imperfecta
OI is a genetic disorder whereby the body of the affected patient either does not produce enough collagen or produces collagen of a poor quality, resulting in extreme bone fragility or what is known as brittle bones, i.e.: bones that fracture repeatedly and easily. For example, a child with severe OI could fracture a leg whilst turning in their sleep. Various treatments exist, including drugs, to aid the production of bone mass, and surgery to help straighten bones and prevent fractures.

Improving the treatment for OI – About the Fassier-Duval Telescopic IM Nail System
The Fassier-Duval Telescopic IM Nail System is an endomedular device aiding patients living with OI. Unlike other commercially available rods, the telescoping range of the F-D system has been increased as has the stability and fixation of the rod, reducing the necessity of revision surgery. The rehabilitation time post-op is reduced compared to that of other systems due to a minimally invasive technique and because the articular joints are unaffected by the surgery. Both reoperation and complication rates at 2 years has been reduced by 3-fold when compared to competitive devices.

Developed by a bio-engineering company (Pega Medical Inc.) and Drs. Francois Fassier (Montreal Shriners Hospital) and Pierre Duval (BMP Hospital) as an alternative telescopic rodding system, this device is indicated for the surgical treatment of paediatric patients diagnosed with OI as well as short-statured patients requiring bone lengthening procedures. Over 70 implants are already in use across Canada, Kuwait, Peru, Ecuador, and Slovenia. An update of the clinical results was presented last week during the meeting of the American Academy of Orthopaedic Surgeons in February in New Orleans, LA.

About Pega Medical
Pega Medical is an ISO 13485-certified privately held company based in Montreal specializing in the design, development, evaluation and manufacturing of orthopaedic medical devices. The company plans the launching into the US market in Q.2 of this year. Commercialization into the EU is planned immediately after receiving CE marking which is now underway.

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