Largest Ever Clinical Trial in Hip Fracture Fixation Completes
One-Year Follow-Up in 1000th Patient
X-BOLT® Revolutionary Hip Fracture Device Granted FDA 510k Approval

(23rd January 2019) – Dublin, Ireland, X-Bolt Orthopaedics, a leading medical device company, today announced the 1000th patient has completed one-year of follow-up in the (n= 1,140 patients) multi-centre randomised controlled trial comparing extracapsular hip fracture fixation devices, known as World Hip Trauma Evaluation 4 (WHITE4), conducted by Oxford University and supported by NIHR Oxford Biomedical Research Centre. The Company's X-BOLT® innovative hip fracture device was also granted FDA 510k approval for marketing in the United States in Q4 2018.

Addressing the growing socio-economic problems of treating hip fractures in frail elderly patients, X-BOLT® is designed to revolutionise current surgical treatment and significantly reduce re-operation rates. Most clinical complications occur with anchorage in the osteoporotic bone and X-BOLT® offers an innovative mechanism that uses wings that expand in situ to offer a rotationally stronger and more secure femoral bone anchorage than traditional screw fixation. A stronger leg to stand on post-surgery allows for faster, fuller and more confident mobilisation of the patient.

Recruitment for WHITE4 commenced in June 2016 and involved 10 centres in UK, collaborating with the Orthopaedic Trauma Society (GB&I), including Oxford, Northumbria, Leicester, Newcastle, South Tees, Frimley Park, Wexham, Coventry, Bristol and Portsmouth. Results are expected to be available in June 2019. Patients were randomised at the time of surgery to receive either a gold standard sliding hip screw (SHS) device or X-BOLT®. Follow-up for all patients occurred at baseline, 4 months and one year following surgery.

Outcome measurements in WHITE4 include the EuroQol 5 Dimension Score (EQ-5D-5L), a validated measure of health-related quality of life, as well as patient mortality, residential status, revision surgery and radiographic measures. This study is a fully powered superiority study that may definitively show the X-BOLT® clinically to be the new gold standard femoral head fixation in hip fracture fixation.

A 100-patient randomised pilot study published in 2016, known as 'WHITE1' at the University of Warwick showed a zero (0%) re-operation rate with the X-BOLT® device, versus a 6% reoperation rate with the traditional sliding hip screw (SHS) in unstable intertrochanteric hip fractures. Full results of WHITE1 are published in the Bone Joint Journal 2016; 98-B: 686-9.

Professor Xavier Griffin, the Chief Investigator of the WHITE 4 trial at Oxford Trauma, commented on the trial, "This is the largest randomised clinical trial in the field of hip fracture fixation and we are delighted to have hit this significant milestone. X-Bolt should be congratulated as an exemplar company for their commitment to working with us using the IDEAL framework in delivering this novel device to market. We look forward to communicating the full results of the trial in June 2019."

Dr. Brian Thornes, CEO of X-BOLT Orthopaedics said, "Hip fractures in the very elderly are a growing unmet medical need with current surgical procedures resulting in poor outcomes that often result in a loss of mobility and independence in vulnerable group of patients. Hip fracture fixation has lacked any significant innovation since Sir John Charnley patented the sliding hip screw in 1955. We believe that the X-BOLT® device has the potential to transform fixation in patients suffering from osteoporosis and hip fractures, providing a significant improvement in mobility and quality of life."

Approximately 1.6 million hip fractures occur worldwide each year and due to an aging population, it is expected this number could reach 6 million by 2050. Each hip fracture episode costs approximately $40,000 (£30,000) in health and social costs. 70% of hip fractures occur in women with a median age of 81yrs. Loss of mobility and independence among hip fracture survivors is profound; less than 50% regaining their previous function and 33% being totally dependent or in a nursing home a year later. Reoperations occur in 6% of patients, resulting in additional costs of approximately $50,000 (£35,000). Reducing the re-operation rate provides a significant opportunity for hospitals and governments to greatly reduce 30-day readmissions and overall healthcare costs, notwithstanding the benefits to patients by improving their quality of life.

The X-BOLT® hip fracture nailing and plating systems were also recently granted FDA 510k approval in Q4 2018, having undergone rigorous mechanical and biocompatibility testing, along with interactions with the US Food and Drug Administration since 2013. This FDA approval now permits the marketing and commercialisation of the X-BOLT® in the United States.

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About X-BOLT Orthopaedics
X-BOLT® Orthopaedics is an Irish medical device company, that has designed and developed a highly innovative and unique range of hip nailing and plating solutions suitable for all hip fractures that require fixation. The X-BOLT® *("Expanding Bolt")* hip fixation system significantly improves anchorage in osteoporotic bone and reduces the requirement for costly repeat surgeries (due to significantly lower reoperation rates), as well as allowing greater confidence to mobile fully weight bearing post operation. X-BOLT® has strong scientific evidence via extensive clinical trials and has received European CE Mark from the British Standards Institute (BSI) and FDA 510k approval for marketing in the US.

Founded and led by Dr. Brian Thornes, an experienced orthopaedic surgeon with extensive development experience having previously invented, developed and licensed the ankle syndesmosis "TightRope" device to Arthrex, Inc (Naples, FL) in 2003. To date, over 300,000 Tightropes have been implanted worldwide, with many top football and rugby professionals amongst its recipients. Recently published multicentre clinical trials have shown that the Tightrope has set the new gold standard for ankle syndesmosis injuries.

The National Institute for Health Research (NIHR) Oxford Biomedical Research Centre (BRC)
NIHR Oxford Biomedical Research Centre (BRC) is based at the Oxford University Hospitals NHS Foundation Trust and run in partnership with the University of Oxford. The NIHR is the nation's largest funder of health and care research. The NIHR:

- Funds, supports and delivers high quality research that benefits the NHS, public health and social care
- Engages and involves patients, carers and the public in order to improve the reach, quality and impact of research
- Attracts, trains and supports the best researchers to tackle the complex health and care challenges of the future
- Invests in world-class infrastructure and a skilled delivery workforce to translate discoveries into improved treatments and services
- Partners with other public funders, charities and industry to maximise the value of research to patients and the economy

The NIHR was established in 2006 to improve the health and wealth of the nation through research, and is funded by the Department of Health and Social Care. In addition to its national role, the NIHR commissions applied health research to benefit the poorest people in low- and middle-income countries, using Official Development Assistance funding.

The Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences (NDORMS)
NDORMS is a multi-disciplinary department focusing on discovering the causes of musculoskeletal and inflammatory conditions to deliver excellent and innovative care that improves people's quality of life. The largest European academic department in its field, NDORMS is part of the Medical Sciences Division of the University of Oxford, and is a rapidly growing community of more than 400 orthopaedic surgeons, rheumatologists and scientists all working in the field of musculoskeletal disorders.

The research work of the department takes place in several locations across the Nuffield Orthopaedic Centre, namely the Botnar Research Centre, and the Kennedy Institute of Rheumatology. The co-location with NHS services puts the department in an excellent position with basic researchers working alongside clinicians. This substantially improves research capacity, improving access for researchers to patients, and facilitating the interaction between clinicians and scientists that is essential for successful medical research. www.ndorms.ox.ac.uk

Contact information:
X-BOLT
Brian Thornes, CEO
+358872384689
brian.thornes@x-bolt.com

Katja Stout, Scius Communications
+44 7789435990
katja@sciuscommunications.com