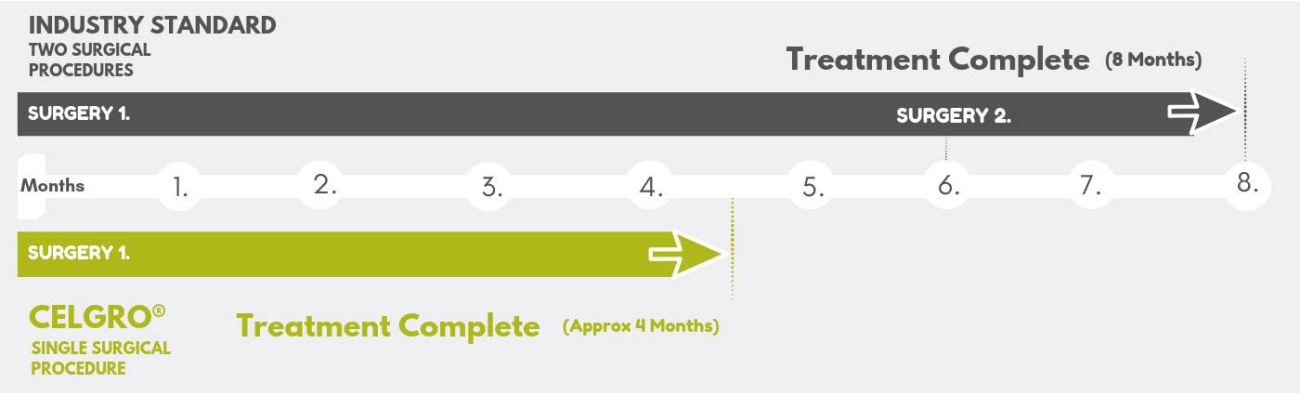
CelGro® accelerates dental implant treatments

- **Patients regain normal oral function and enjoy a normal diet** following CelGro® bone regeneration treatment.
- **Patients experience a 40% reduction in dental implant treatment timeframe.**
- Results further validate **CelGro®** as the **superior medical device for bone and soft tissue repair.**
- **CelGro® continues to gain traction in Europe,** with strategic partnering activities ongoing.

Perth, Australia; 19th June 2019: Regenerative medicine company Orthocell Limited (ASX:OCC, "Orthocell", or the "Company") is pleased to announce all patients have successfully completed the CelGro® single-stage dental implant study ("Marketing Study") designed to assess effectiveness and predictability in accelerating treatment timeframes. The Marketing Study follows the successful two-stage dental implant trial and market authorisation (CE Mark) of CelGro® in the EU for dental bone and soft tissue applications. The Marketing Study results further validate CelGro® as the superior medical device for bone and soft tissue repair and will assist in driving market adoption.

The 10 patients treated in the Marketing Study had previously suffered, in some cases for many years, from damaged, missing or diseased teeth. Symptoms prior to treatment included severe irritation, bleeding gums, an inability to chew or eat certain foods (eg: steak, citrus, frozen goods) and enjoy a normal diet.

After surgery with CelGro®, the impact on patients' lives was significant. All patients successfully generated enough new bone to stabilise their implants and complete treatment in approximately four months – **almost half the time of the usual two-stage (eight months) dental implant treatment.** The diagram below compares the single stage and two stage surgical dental implant procedures.



Patient Peta Nancarrow said: "My dental implant procedure was a great success. Prior to treatment I couldn't chew properly and was suffering from an inability to eat certain foods. Dr Allan suggested I participate in the CelGro® study as it might improve and accelerate treatment. I'm so glad I did. I have regained the ability to chew all types of food and I am back enjoying a normal diet. I also avoided a second surgical procedure."

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Dr Brent Allan said: "The qualities of the CelGro® membrane have enabled me to move from a two-stage surgical procedure to a single-stage surgical procedure. It has reduced the timeframe and cost for patients to achieve their goals. This positive progression has been made possible due to the rapid and superior quality bone regeneration and handling qualities provided by the CelGro® membrane."

Information about the CelGro® bone regeneration study and single stage dental implant procedures

In 2018 the Company announced clinical trial results demonstrating CelGro® guides superior quality bone formation when used to treat bone defects during two-stage dental implant treatments (26% better quality newly formed bone when compared to market leading comparative product). Following this successful trial, Orthocell conducted the Marketing Study to demonstrate CelGro® can support rapid and high-quality guided bone regeneration (GBR) when used in single-stage dental implant treatments. The Marketing Study was undertaken in partnership with Dr Brent Allan, a leading Australian maxillofacial surgeon, and Professor Ming Hao Zheng from the University of Western Australia. .

Results from the Marketing Study indicate that single-stage GBR treatment with CelGro® results in rapid formation of high quality, mature bone around the dental implants. All patients successfully generated enough new bone to stabilise their implants and complete their treatment in an average of approximately four months – **this is almost half the time of the usual two-stage (eight month) dental implant treatment.** Diagnostic imaging confirmed vertical and horizontal bone formation around the dental implant to facilitate the single stage procedure.

GBR is performed with dental implant treatment when there is not enough bone to securely anchor and stabilise implants in the jaw. The traditional two-stage procedure involves an initial surgery to place the implant into the jaw. A second surgery, approximately six months later to allow bone regeneration to occur, is required to place the implant abutment connecting the implant to the prosthetic tooth. The procedure is completed four-to-six weeks later when the prosthetic tooth is installed. Single-stage procedures are shorter and avoid a second surgery and anaesthetic, by placing the implant and abutment in the jaw at the same time. The prosthetic tooth is placed four-to-six months later once there is sufficient bone to stabilise the implant.

Orthocell Managing Director, Paul Anderson, said: "CelGro®'s ability to deliver superior bone growth has the potential to revolutionise dental implant techniques and is highly desired by physicians and potential partners. The latest results provide further evidence that positions CelGro® as the best in class collagen membrane."

CelGro® addressable market in bone repair and dental implant treatment

Accelerated (single-stage) dental implant treatment is of significant clinical interest to the dental community because of the potential improvements in efficiency and efficacy of surgical procedures. CelGro® facilitates predictable and rapid bone regeneration underpinning dental implant procedures in as little as three months, and at lower cost to the patient. The shorter timeframe is of particular value when implant treatment is used to restore normal function, allow a return to a normal diet and restore a patient's smile.

Dental implants are an effective and rapidly growing area of orthodontic treatment. CelGro®'s dental bone regeneration addressable market is estimated to be worth more than US$900m p.a. (representing a 50% increase on previous estimates), with approximately 4.3 million procedures that utilise these types of scaffolds being completed each year. The 50% increase in the estimated addressable market is driven by advances in GBR techniques and dental implant technology. BioGide®, the current leading comparable collagen membrane generates approximately €50 million per annum in dental bone graft sales in Europe alone.

The company believes CelGro® represents a breakthrough in bone and soft tissue reconstruction and is an integral component in the rapidly advancing dental implant market. Market growth is expected to be underpinned by surgeon and patient preference for single-stage implant treatments compared to the traditional two-stage procedure.

Next Steps

The very positive data comes at a time when the Company is active in partnering discussions and will support the Company in gaining traction in key markets including the EU, US and Australia.

Orthocell intends to leverage CelGro®'s ability to guide superior quality bone formation and use the supplementary marketing data generated from the single-stage performance study to further position CelGro® as the best-in-class collagen membrane for dental bone and soft tissue repair. The performance study underpins the compatibility and versatility of CelGro® as a platform technology and highlights the potential to extend Orthocell's innovative dental product range.

The Company is leveraging the EU regulatory approval and finalising its submission for US regulatory clearance (510K).

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For more information, please contact:

General enquiries

Paul Anderson
Orthocell Limited
Managing Director
P: +61 8 9360 2888
E: paulanderson@orthocell.com.au

Media enquiries

Haley Chartres
Hales[2] Communications
P: +61 423 139 163
E: haley@h-squared.com.au

About Orthocell Limited

Orthocell is a regenerative medicine company focused on regenerating mobility for patients by developing products for the repair of a variety of bone and soft tissue injuries. Orthocell's portfolio of products include TGA-licensed cell therapies Autologous Tenocyte Implantation (Ortho-ATI®) and Autologous Chondrocyte Implantation (Ortho-ACI®), which aim to regenerate damaged tendon and cartilage tissue. The Company's other major product is CelGro®, a collagen medical device which facilitates tissue repair and healing in a variety of orthopaedic, reconstructive and surgical applications. Orthocell recently received European regulatory approval (CE Mark) for CelGro®. The collagen medical device can now be marketed and sold within the European Union for a range of dental bone and soft tissue regeneration procedures and is being readied for first approval in the US and Australia.

For more information on Orthocell, please visit www.orthocell.com.au or follow us on Twitter **@Orthocellltd** and LinkedIn www.linkedin.com/company/orthocell-ltd=