## ASX ANNOUNCEMENT/MEDIA RELEASE 16 FEBRUARY 2021



# PILOT STUDY INDICATES BENEFITS OF AROA BIOSURGERY'S MYRIAD<sup>TM</sup> IN SURGICAL RECONSTRUCTION OF CHRONIC WOUNDS

### **HIGHLIGHTS**

- Aroa's Myriad™ may be used successfully under a tissue flap to reduce surgical complications in the flap reconstruction of chronic wounds, including pressure injuries and non-healing surgical wounds.
- Pilot study published in the journal Frontiers of Surgery, builds on other recent publications on the efficacy of Myriad™ in surgical treatment of Hidradenitis Suppurativa (HS) and exposed vital structures.

Soft tissue regeneration company Aroa Biosurgery Limited (ASX:ARX, 'Aroa' or the 'Company') has gained further validation for Myriad™, a device for soft tissue reconstruction, with a new pilot study indicating that it may be used successfully under a tissue flap to reduce surgical complications in the reconstruction of challenging, non-healing chronic wounds.

The findings have been published in journal *Frontiers of Surgery,* in an article titled "Case Report: Surgical Closure of Chronic Soft Tissue Defects Using Extracellular Matrix Graft Augmented Tissue Flaps". It was based on a pilot study undertaken by plastic surgeon Dr Michael Desvigne (MD) and colleagues from Abrazo Arrowhead Hospital in Phoenix, Arizona.

The study can be found online at <a href="https://www.frontiersin.org/articles/10.3389/fsurg.2020.559450/full">https://www.frontiersin.org/articles/10.3389/fsurg.2020.559450/full</a>.

The pilot study saw a total of nine non-healing wounds, including those caused by pressure injuries and surgical wounds, reconstructed using Aroa's Myriad™ device as an implant under a soft tissue flap. Only one minor surgical complication was observed, and all wounds went on to fully heal, even when Myriad™ was used in a contaminated field. By contrast, a retrospective review of the flap reconstruction of chronic pressure injuries reported a complication rate of 58%.

The positive findings follow recently announced studies demonstrating the efficacy of Myriad™ in the surgical treatment of the high-incidence inflammatory skin condition Hidradenitis Suppurativa (HS), and exposed vital structures.

Dr Desvigne said that, overall, the findings supported a thesis that the use of Myriad™ in flap reconstruction of chronic wounds may reduce surgical complications typically seen.

"Myriad™ is engineered from Aroa ECM™ which is known to modulate destructive tissue proteases, rapidly integrating into the wound base to provide healthy, well vascularized tissue, while the reduced surgical dead space under the flap reduces the likelihood of fluid accumulation and seroma formation," said Dr Desvigne.

The pilot study included the surgical closure of three pressure injuries, which are estimated to affect 1 to 3 million people in the USA, with prevalence estimates among hospitalized patients ranging from 5% to 15%.

Chronic non-healing wounds are a significant burden on the health system and significantly reduce the patient's quality of life. They can be a particular issue if the patient has co-morbidities that hamper the normal healing process, such as diabetes or vascular disease. When surgical intervention is taken in the most severe cases, it is often compromised by the poor tissue quality that can lead to post-operative surgical complications such as dehiscence ('tissue breakdown'), infection, seroma, and recurrence.

Aroa Founder and CEO Brian Ward said the latest study supports the growing body of clinical evidence for the efficacy of Myriad™ and the role it can play in positive outcomes for patients.

"This latest study showing the potential benefits of Myriad™ in flap reconstruction of chronic wounds builds on two other clinical studies published since November last year showing the efficacy of Myriad™ in the surgical treatment of serious cases of the inflammatory skin condition hidradenitis suppurativa (HS) and when patients underwent surgical reconstruction to achieve coverage over exposed vital structures such as bone and tendon.

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"In conjunction with launching Myriad™ in the United States in February 2020, gaining EU regulatory approval in late July 2020 and India in mid-December 2020, this growing body of clinical evidence supports the central role of Myriad™ in our commercial growth strategy as surgical procedure volumes recover post-COVID-19 and make advanced regenerative healing more accessible to more patients," Mr Ward said.

Aroa has five commercial products approved for sale in the US based on its ECM technology, which has been used in more than four million procedures targeting chronic wounds, hernia and soft tissue reconstruction. Earlier pre-clinical studies have shown that the Aroa ECM™ technology includes over 150 different components known to aid wound repair, blood vessel formation and attract stems cells. Aroa has regulatory clearance in more than 40 countries.

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Authorised on behalf of the Aroa Biosurgery Board of Directors by Brian Ward, CEO.

#### **About Aroa Biosurgery:**

Aroa Biosurgery is a soft-tissue regeneration company that develops, manufactures, sells and distributes medical and surgical products to improve healing in complex wounds and soft tissue reconstruction. Committed to 'unlocking regenerative healing for everybody', its products are developed from the Company's proprietary Aroa ECM™ technology platform, a novel extracellular matrix biomaterial derived from ovine (sheep) forestomach. Clinically proven with peer reviewed publications, Aroa's products have been used in more than four million procedures to date, with distribution into its key market of the United States by Appulse and Tela Bio. Founded in 2008, Aroa is headquartered in Auckland, New Zealand and is listed on the Australian Securities Exchange (ASX:ARX). www.aroabio.com/

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<sup>&</sup>lt;sup>i</sup> Mondragon N, Zito PM. Pressure Injury. [Updated 2020 Sep 29]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2020 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK557868/