ASX ANNOUNCEMENT
18 October 2022

PRE-CLINICAL STUDY OF ENIVO™ SHOWS POTENTIAL FOR MANAGING POST-SURGICAL 'DEAD SPACE'

Highlights

- ENIVO™, a novel system developed by AROA for managing post-surgical 'dead space', has shown potential for promoting tissue apposition and reducing seroma formation in a challenging pre-clinical model.
- Seromas are a common post-surgical complication which can disrupt healing and increase pain, oedema (swelling) and poor cosmetic outcomes. They can also lead to more severe complications such as wound dehiscence, infection and necrosis of overlying tissue.
- Use of ENIVO resulted in near complete dead space closure at the conclusion of treatment, with a median seroma area of 2% and volume of near 1.3mL, compared to an area of 98% and volume of 188.5mL for the Standard of Care treatment.
- All nine (100%) cases were successfully treated with the ENIVO system, with approximately three times more fluid removed using ENIVO over the course of treatment when compared to current Standard of Care.
- The peer-reviewed study in *ePlasty* journal supports AROA's plan to proceed with a pilot clinical study, and US FDA submission by the end of the calendar year.

Aroa Biosurgery Limited (ASX: ARX, 'AROA or the 'Company') has this week marked the publication of a peer-reviewed pre-clinical study to assess the safety and effectiveness of the ENIVO system for managing clinical 'dead space'. This has demonstrated potential for promoting tissue apposition and reducing the formation of seromas[1] in post-surgical sites.

The ENIVO system employs an external vacuum device coupled to a specially designed AROA ECM™ implant device to draw separated tissue surfaces together and remove excess fluids from the treatment site.

This proprietary system has been completely developed in-house by AROA's R&D Engineering team, demonstrating the wide capability that exists within AROA in addition to its existing scientific-focused R&D teams.

AROA CEO, Dr. Brian Ward says, "We're delighted with the evidence that ENIVO can promote tissue apposition to reduce the incidence and impact of seromas which are very common after surgery and can lead to extended hospitalisation and treatment costs due to the complications they cause," says Dr. Ward.

Seromas can result in disrupted healing, increased pain, oedema, and poor cosmetic outcomes, leading to more severe complications such as wound dehiscence, infection, and necrosis of the overlying tissue (flap failure).

[1] Seromas form in the dead space that remains following the surgical separation and excision of soft tissue, where any damaged vessels can fill the resulting subcutaneous void with plasma and lymph fluid.

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The findings of the study are published in an article titled "*Evaluation of Tissue Apposition and Seroma Prevention in an Ovine Model of Surgical Dead Space using a Novel Air-Purged Vacuum Closure System"* published in the Journal *ePlasty,* a peer-reviewed publication spanning the fields of burns, and plastic, reconstructive, vascular and dermatologic surgery, tissue repair, and surgical wound healing.

The study is available online, here.

Study findings

This pre-clinical study assessed the effectiveness of ENIVO at preventing seromas and supporting tissue apposition (re-approximation of separated tissue layers) side-by-side with the use of a closed surgical drain within a "challenging large defect model of surgical dead space management and seroma prevention."

Closed surgical drain devices are the current standard of care (SoC) for seroma prevention at a closed surgical site. The study found that treatment with the ENIVO system resulted in significantly reduced seroma area and seroma volume at days 7 and 14 when compared to the SoC group.

Use of ENIVO resulted in near complete dead space closure at the conclusion of treatment (two weeks post-treatment), with a median seroma area of 2% and median seroma volume of 1.3 mL, compared to an area of 98% and volume of 188.5 mL for the Standard of Care treatment.

Significantly, approximately three times more fluid was removed by the ENIVO treatment device than the SoC group, and at day 28, all nine (100%) treatments of tissue defects were judged clinically successful with use of the ENIVO system, versus only six out of ten (60%) for the SoC treatment. No post-operative complications were reported in either the ENIVO or SoC treatment group following the completion of the study.

Commercialisation

AROA CEO, Dr. Brian Ward says the encouraging findings affirm AROA's commitment to commercialise ENIVO following substantial investment in its development over the last four years.

"We consider that ENIVO has the potential to match the scale of AROA ECM as an entire treatment platform and reduce the impacts of tissue loss through surgery for potentially thousands of patients who undergo invasive surgeries in the United States each year," Dr. Ward says.

The Company estimates the total addressable market in the United States to be in excess of US$1 billion.

The Company has commenced work on a pilot clinical trial and is targeting regulatory clearance submission to the US Food and Drug Administration (FDA) by the end of the calendar year.

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

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About Aroa Biosurgery:
Aroa Biosurgery is a soft-tissue regeneration company committed to 'unlocking regenerative healing for every*body*'. We develop, manufacture, sell and distribute medical and surgical products to improve healing in complex wounds and soft tissue reconstruction. Our products are developed from a proprietary AROA ECM™ technology platform, a novel extracellular matrix biomaterial derived from ovine forestomach. AROA has six patented product families selling in the US based on its AROA ECM technology, targeting chronic wounds, hernia, soft tissue and breast reconstruction. AROA's products have been used in more than 5.6 million procedures to date, with distribution into our key market of the United States via our direct sales force and our partner TELA Bio. AROA has regulatory approvals in 49 countries. 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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