Transplants and Grafts

Safety and Tolerability of an Off-the-Shelf Autologous Adipose Tissue Biomaterial Delivered Subcutaneously in Healthy Volunteers

Although today's Service members utilize the strongest and most advanced body armor, there continue to be challenges in preventing severe facial injuries. Researchers at Johns Hopkins University (Baltimore, Maryland) and Aegeria Soft Tissue (Baltimore, Maryland) designed an off-the-shelf adipose-derived biomaterial for simple injection into tissue defects with physical properties to retain volume and biological properties to induce cell migration into the implant and stimulate new tissue formation (Figure 1). The material was developed in close collaboration with surgeons/end users to define design parameters and evaluated using methods of biomaterial analysis, cellular compatibility, and preclinical animal testing. Regulatory milestones include Request for Designation and Investigational New Drug Application submissions to the U.S. Food and Drug Administration (FDA), and responses to FDA feedback regarding trial design and development of additional batch testing methods for manufacturing quality control. Clinical grade manufacturing and sterilization has been completed.

Results of the clinical testing validated safety and Phase 2 studies are now exploring efficacy of a new technology for soft tissue reconstruction of warrior injuries that may occur in all regions of the body.

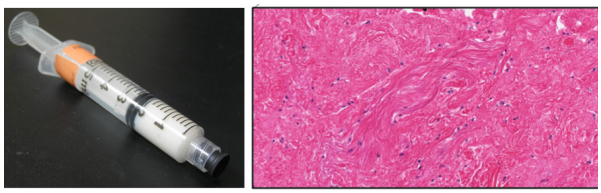

FIGURE 1: GMP-produced biomaterial implant and cell infiltration into the implant after 18 weeks implantation in a healthy human volunteer. (Figure used with permission from the authors)

Researchers have completed a Phase 1 safety trial of the injectable soft tissue regeneration technology for repair of injuries in the craniofacial region (*Anderson et al. 2017, Anderson et al. 2016*). This first in human study confirmed clinical safety of the material and injection procedure in healthy volunteers. A Phase 2 trial is currently being initiated to evaluate efficacy in volumetric tissue reconstruction in a dose escalation study.

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