**CLINICAL NEED**

Individuals suffering from severe temporomandibular joint (TMJ) disc disease experience painful clicking or locking that can dramatically affect quality of life. Total TMJ reconstruction is often the last-resort surgical intervention for the irreparably damaged joint. Current therapies include joint replacement using alloplastic implants or autogenous grafts; however, long term outcomes with alloplastic implants are unclear, while autogenous grafts are associated with donor site morbidity.

**SOLUTION**

University of Pittsburgh team of Alex Almarza, PhD, Stephen Badylak, DVM, PhD, MD, William Chung, DDS, MD, and Bryan Brown PhD is developing an extracellular matrix (ECM)-based scaffold device for the reconstruction of the TMJ. In particular, the device is designed to replace the meniscus of the TMJ by inducing the formation of new, patient-specific, functional tissue formation.

**COMPETITIVE ADVANTAGE**

Unlike currently available alloplastic implants, ECM-based device is biodegradable, and mimics the shape and size of native TMJ meniscus, without the need for autologous tissue harvesting. The device has been validated in canine and porcine models, where the scaffold demonstrated rapid transformation into a fibrocartilaginous tissue with biomechanical and biochemical properties similar to the native TMJ disc, as well as elicited formation of near-normal tissues in only one month following implantation.

**ITP SUPPORT**

The long-term objective of this program is the development of a safe and effective therapeutic option for reconstruction of the TMJ disc. In preparation for submission to the FDA, the ITP program will support the validation of devices made in a GMP facility, and for the submission of a pre-IDE application to the FDA.

**CLINICAL TRANSLATION PATHWAY**

**Publications:**

**Intellectual Property:** US 9,314,340 Joint bioscaffolds

**Regulatory Pathway:**
- Anticipated: Device, IDE to enable PMA

**Commercialization Strategy:**
- In development with the MPWRM Commercialization/Market Needs Core

**Product Launch Strategy:**
- In development with the MPWRM Commercialization/Market Needs Core

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