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Denteric Announces FDA IND Clearance for GPV381, a First-in-Class Therapeutic Vaccine Targeting Gingipain-Driven Inflammation in Periodontitis

- IND clearance enables initiation of U.S. Phase 2 clinical study in advanced periodontitis
- Targets upstream drivers of immune dysregulation in a disease affecting ~90 million Americans and over 1 billion people globally
- Potential to introduce a disease-modifying approach in a field historically limited to mechanical intervention

Melbourne, Australia – Denteric today announced that the U.S. Food and Drug Administration (FDA) has cleared the Investigational New Drug (IND) application for GPV381, a first-in-class therapeutic vaccine targeting gingipain toxins, key upstream drivers of immune dysregulation and chronic inflammation in periodontitis. IND clearance enables the initiation of a Phase 2 clinical study in the United States.

Periodontitis is one of the most prevalent chronic inflammatory diseases globally, affecting approximately 90 million individuals in the United States, including an estimated 14 million with severe disease, and more than 1 billion people worldwide. The disease is associated with over $150 billion in annual direct and indirect costs in the U.S. alone. Despite its scale and systemic implications, treatment has remained largely unchanged, relying on mechanical plaque removal and surgical intervention rather than targeting underlying disease biology.

GPV381 is designed to generate antibodies against gingipain toxins produced by *Porphyromonas gingivalis*, which are increasingly recognized as central mediators of immune disruption and sustained inflammatory signaling in periodontitis. By neutralizing these toxins, GPV381 aims to restore immune homeostasis, reduce pathologic inflammation, and enable clinically meaningful improvements in periodontal health.

“IND clearance marks an important milestone as we advance GPV381 into clinical evaluation,” said Sean McLoughlin, Chief Executive Officer of Denteric. “Our Phase 2 study is designed to assess whether targeting gingipain-driven biology can meaningfully alter

disease progression and deliver improved clinical outcomes for patients with advanced periodontitis."

The planned Phase 2 study is expected to evaluate safety, immunogenicity, and key clinical endpoints in patients with advanced periodontitis, including measures of periodontal pocket depth, tissue healing, and progression of bone loss. The study will also assess local and systemic inflammatory biomarkers to further characterize the impact of gingipain inhibition on disease biology.

"Periodontitis has long been recognized as a chronic inflammatory condition with significant consequences for both oral and systemic health, yet therapeutic innovation has been limited," said Dr. Paul Cockle, Chief Scientific Officer of Denteric, "Targeting upstream drivers of immune dysfunction represents a promising new approach, and clinical evaluation of gingipain-targeted therapy is an important step toward determining whether this strategy can change the course of disease."

Beyond oral health, gingipain activity has been implicated in systemic inflammatory conditions, including Alzheimer's disease, diabetes, and cardiovascular disease, underscoring the broader relevance of this therapeutic target.

About GPV381

GPV381 is a first-in-class therapeutic vaccine designed to generate antibodies targeting gingipain toxins produced by *Porphyromonas gingivalis*. By addressing upstream drivers of immune dysregulation, GPV381 is intended to enable a disease-modifying approach to the treatment of periodontitis.

About Denteric

Denteric is a clinical-stage biotechnology company developing immunotherapeutic approaches to address the underlying biological drivers of chronic inflammatory diseases.

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