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Development of a novel protein therapeutic for regenerative medicine

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MG53 is a tripartite motif (TRIM) protein that plays essential roles in plasma membrane repair. It binds to phosphatidylserine and facilitates the formation of repair patches at sites of membrane disruption. Genetic ablation of MG53 leads to defective repair and tissue regenerative capacity. Native MG53 is present in blood circulation, suggesting that parenteral administration of recombinant human MG53 (rhMG53) is unlikely to induce an immune response and potentially be a safe biological reagent for treatment of tissue injuries. We found that systemic delivery of rhMG53 protein provides a dose-dependent protection against injuries to multiple organs, including injury to limb muscle, acute lung injury, acute kidney injury, myocardial infarction. Topical application of rhMG53 can facilitate wound healing and reduce scarring. A university spin-off biotechnology company named TRIM-edicine was founded with an exclusive license of MG53-related intellectual properties, aiming to commercialize the application of rhMG53 for human diseases. TRIM-edicine has obtained guidance from the FDA in pre-IND meetings regarding the pathway for moving forward rhMG53 to human studies. The chemistry, manufacturing, and controls (CMC) for purification and scale-up production of rhMG53 has been established. Informal pharmacokinetic and toxicology assessments of rhMG53 in rodent and large animal models revealed that repetitive administration of rhMG53 is safe.

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