Gene Biotherapeutics Announces Sale Of Excellagen Technology Platform; Retains Commercialization Rights For Greater China And Russian Federation

SAN DIEGO, Sept. 5, 2018 /PRNewswire/ -- Gene Biotherapeutics Inc. (formerly Taxus Cardium Pharmaceuticals Group Inc./trading symbol: CRXM) today announced that it has entered into an agreement with the U.S.-based Olaregen Therapeutix Inc. covering the sale of Excellagen® flowable dermal matrix for wound healing. Olaregen is a special purpose entity which was formed by an unaffiliated investment group to acquire and commercialize advanced wound healing therapeutics for multiple vertical markets. Gene Biotherapeutics retains the exclusive rights to develop and commercialize the Excellagen dermal matrix for wound healing in greater China, the Russian Federation and 11 other Eurasian countries within the Commonwealth of Independent States consistent with the indications for use as set forth in the Excellagen U.S. FDA 510(K) clearance letter and a US patent issued October 10, 2017.

Under the terms of the agreement, Gene Biotherapeutics will be entitled to a total consideration of up to $4,000,000, consisting of an upfront cash payment totaling $650,000 and $3,350,000 in additional consideration that would consist of royalties on worldwide net sales, and accelerated royalties in the form of lump sum cash payments based on capital investments received by Olaregen or the sale of the Excellagen technology platform to a third party.

Emerging Medical Need for Advanced Wound Care in Asian Markets

A clinical study conducted by researchers at eight leading hospitals and medical centers representing nearly all geographic regions across China has concluded that diabetic foot ulceration represents a serious problem in China, and that more intensive surveillance, more aggressive treatment, and earlier referral to specialty care are required to improve patient outcomes. The study reported that there are approximately 114 million Chinese adults with diabetes and 493 million Chinese adults with pre-diabetes. The study shows that the prevalence of diabetic foot ulcers has increased from 4.91% in 1996 to 35.3% in 2008 and has been "a heavy burden for health care resources, with an average hospital stay of 31 days and a medical cost of 17,181 yuan RMB." It was also reported that the incidence of diabetic foot ulcers and amputation in China are much higher that of Western countries [Jiang et al., Wound Repair and Regeneration, 2015. DOI: 10.1111/wrr.12263].

Excellagen® Advanced Dermal Wound Matrix

Excellagen® is an FDA-cleared, flowable dermal matrix indicated for the treatment of hard to heal wounds such as diabetic foot ulcers and pressure ulcers as well as other dermal wounds. Excellagen is supplied in the form of a physiologically formulated homogenate of purified bovine dermal collagen (Type I) in its native 3-dimensional fibrillar configuration. Excellagen® can activate platelets, triggering release of essential growth factors and is capable of providing a structural scaffold for cellular infiltration and migration, significantly accelerating the growth of granulation tissue. Excellagen's unique flowable fibrillar collagen formulation is topically applied through easy-to-control, pre-filled sterile syringes and is designed for application at once weekly intervals. Excellagen® has been designated as a skin substitute (bearing a unique product Q Code), in accordance with the standards established by the U.S. Centers for Medicare and Medicaid Services (CMS).

On June 7, 2017, Gene Biotherapeutics received a Notice of Allowance from the U.S. Patent and Trademark Office (USPTO) for a new patent (U.S. Patent #9,782, 457) entitled "Flowable Formulations for Tissue Repair and Regeneration." The patent application includes claims covering methods to utilize formulations encompassing Excellagen [2.6%] as a topically applied flowable fibrillar collagen matrix for wound repair by promoting localized release of platelet derived growth factors and providing an in situ microstructural scaffold for cell migration. On February 12, 2018, Gene Biotherapeutics received a Notice of Allowance for a patent with the same title and similar claims from the State

Intellectual Property Office of China (CN Application #2013800634138). The U.S. patent is transferred to Olaregen as part of this transaction, whereas Gene Biotherapeutics retains the China patent.

Olaregen Therapeutix Inc.

Olaregen Therapeutix, Inc. is newly formed regenerative medicine company focused on the development, manufacturing and commercialization of products that fill unmet needs in the current wound care market. The company aims to provide advanced healing solutions that substantially improve medical outcomes while lowering the overall cost of care. Olaregen's first product introduction, Excellagen® (flowable dermal matrix) is a topically applied product for dermal wounds and other indications. Excellagen is a FDA 510K cleared device for a broad array of dermal wounds, including partial and full thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor sites/ grafts, post-Mohs surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns and skin tears) and draining wounds, enabling Olaregen to market Excellagen in multiple vertical markets. Additionally, Excellagen can serve as an Enabling Delivery Platform for pluripotent stem cells, antimicrobial agents, small molecule drugs, DNA-Based Biologics, conditioned cell media and peptides.

Olaregen's initial focus will be in advanced wound care including diabetic foot ulcers (DFU), venous leg ulcers and pressure ulcers. Future products focusing on innovative therapies in bone and joint regeneration comprise the current pipeline. The company's mission is to become a significant force in regenerative medicine and advance the science of healing.

Gene Biotherapeutics Inc.

Gene Biotherapeutics (formerly Taxus Cardium Pharmaceuticals Group Inc.) is an operating company that will maintain royalty and cash entitlement rights and direct equity investments and redeploy cash payments and capital gains from the sale of portfolio investments to acquire and commercially develop new and innovative gene-based therapeutics. Its business portfolio currently consists of (1) Activation Therapeutics which is entitled to royalties received from the transaction with Olaregen Therapeutix, announced today and the revenues and cash payments that may result from the successful commercialization of Excellagen in Eurasian countries, and (2) Angionetics, an 85%-owned business unit focused on the clinical advancement and commercialization of Generx®, an interventional cardiology, angiogenic gene therapy Phase 3 product candidate designed for the potential treatment of patients with refractory angina due to advanced coronary artery disease. The Company has indicated that it plans to externally finance the further clinical development and commercialization of Generx, which could include an initial public offering.

Angionetics Inc.

Angionetics is a biotechnology company, recently formed by Gene Biotherapeutics, that has been designed to affect an asset "value unlock" of its undervalued technology platforms. As Angionetics advances forward with its plan to operate as a company independent of Gene Biotherapeutics, it will focus on the clinical and commercial development of angiogenic, gene- based bio-therapeutics for the treatment of up to an estimated 1.2 million patients in the U.S. who have late-stage coronary artery disease and refractory angina, as well as other medical conditions due to myocardial ischemia.

Angionetics' Generx regulatory dossier on file with the FDA represents one of the most extensive and advanced DNA-based clinical data platforms ever compiled, positioning Angionetics as the world's leader in the field of cardiovascular angiogenic gene therapy, covering four FDA-cleared clinical studies conducted at 100 medical centers worldwide, that have evaluated more than 650 patients, and generated over 2,500 patient years of safety data. For more information, please see Angionetics' most recent investor presentation: Angionetics Investor Presentation.

Forward-Looking Statements

Except for statements of historical fact, the matters discussed in this press release are forward looking and reflect numerous assumptions and involve a variety of risks and uncertainties, many of which are beyond our control and may

cause actual results to differ materially from expectations. For example, there can be no assurance that the Excellagen product will be accepted for registration for marketing and sales in the Asian countries set forth in this press release or that Excellagen will be accepted for widespread use in such countries, and there can be no assurance that results or trends observed in one clinical study or procedure will be reproduced in subsequent studies or in actual use; that new clinical studies will be successful or will lead to approvals or clearances from health regulatory authorities, or that approvals in one jurisdiction will help to support studies or approvals elsewhere; that the company can attract suitable commercialization partners for our products or that we or partners can successfully commercialize them; that our product or product candidates will not be unfavorably compared to competitive products that may be regarded as safer, more effective, easier to use or less expensive or blocked by third party proprietary rights or other means; that the products and product candidates referred to in this report or in our other reports will be successfully commercialized and their use reimbursed, or will enhance our market value; that new product opportunities or commercialization efforts will be successfully established; that third parties on whom we depend will perform as anticipated; that we can raise sufficient capital from partnering, monetization or other fundraising transactions to maintain our stock exchange listing or adequately fund ongoing operations; or that we will not be adversely affected by these or other risks and uncertainties that could impact our operations, business or other matters, as described in more detail in our filings with the Securities and Exchange Commission. We undertake no obligation to release publicly the results of any revisions to these forward-looking statements to reflect events or circumstances arising after the date hereof.

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