REGENEUS IS SOLIDIFYING OUT-LICENSING PARTNERING AND LOOKING TO COMMENCE A JAPANESE PHASE II TRIAL

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English Version

Cellular Therapy for Knee OA

Mr. John Martin, CEO of the Australian regenerative medicine venture company, Regeneus, agreed to be interviewed by this newspaper and relayed his plan to locate an out-license partner for the firm's Knee Osteoarthritis (OA) cellular therapy. Progenza is garnering interest from a number of companies on the back of Regeneus' Australian Phase I data, which showed possible disease modifying properties. AGC Asahi Glass already has exclusive manufacturing rights for Progenza in Japan.

Progenza is a cellular therapy which is manufactured using adipose-derived mesenchymal stem cells (MSCs) from healthy donors, and utilises a proprietary culturing process. The resulting cellular therapy is injected directly into a patient's knee. The therapy's anticipated MoA involves the anti-inflammatory effects of biologically active substances secreted by the MSCs, and Regeneus hopes to be able to use the therapy to address various inflammatory conditions, including OA.

The firm recently reported on the results of their Australian Phase I clinical trial of Progenza in OA. The trial, which consisted of 20 OA patients and included a placebo cohort, was able to meet its primary endpoints in Safety and Tolerability. Furthermore, the firm was also able to report significant results within their secondary endpoints of Efficacy, whereby they rated the participant's pain using VAS and WOMAC scores. Additionally, the firm was also able to show an increase in total cartilage volume in the low-dose cohort, hinting at possible disease modifying properties of Progenza.

Taking the positive results from their Phase I trial, Regeneus is currently planning on conducting Phase II trials in Japan. AGC Asahi Glass has already licensed-in exclusive manufacturing rights for Progenza in Japan last December, and will be tasked with preparing GMP grade investigational product (IP) for the Japan trial in addition to part-funding the manufacturing-related costs for getting Progenza GMP ready in Japan. AGC Asahi Glass is looking to gain experience/expertise in regenerative medicine contract manufacturing, thereby expanding their current biological CMO capabilities, through this partnership covering Progenza.

Regeneus is looking to ascertain a further partner in Japan to whom which they will out-license exclusive development/commercialisation rights to, and will look for said partner to drive the Phase II Japanese clinical trial. Regeneus also hopes to take advantage of the conditional approval process recently put in place for regenerative medical products in Japan.

The firm's CEO, Mr. John Martin mentioned to this newspaper that "the possibility of disease modification that we've been able to see from the results of our Australian Phase I trial has piqued the interest of numerous potential partners, who we are in discussions with."

Besides OA, Regeneus is also looking at neuropathic pain, for which they are currently conducting a pre-clinical study, as a possible indication for Progenza. Should the pre-clinical study prove to be successful, the firm will consider bringing this second indication down the same path that was taken for OA; an Australian Phase I, followed by a Japan/US Phase II.

年内にも日本導出決定

膝ＯＡ向け細胞医薬

豪レジニアス 国内でＰ２実施へ

マーティン氏

オーストラリアの再生医療ベンチャー、レジニアスのジョン・マーティンCEO（最高経営責任者）は本紙の取材に応じ、変形性膝関節症（膝OA）向け細胞医薬品「プロジェンザ」の日本における導出先を今年内にも決める方針を明らかにした。プロジェンザは豪州で実施した第1相臨床試験（P1）で疾患修飾作用が認められたことから、多くの製薬企業が関心を示している。プロジェンザの日本での独占製造権は旭硝子が保有している。

プロジェンザは、健常人ドナーから採取した脂肪細胞に含まれる間葉系幹細胞（MSC）を独自の培養プロセスで製剤化した細胞医薬品。注射によって直接患者の膝関節内に注入する。MSCが分泌する生理活性物質を介した抗炎症作用を期待しており、膝OAを含めたさまざまな炎症性疾患への応用を目指している。

このほど、豪州で実施していた膝OAを適応症としたP1の結果を公表。膝OA患者20人を対象としたプラセボ対照試験で、主要評価項目である安全性、忍容性が確認された。副次評価項目である有効性では、疼痛の評価指標であるVAS値とWOMACスコアともに有意な改善が認められた。MRI画像評価では同剤低用量で軟骨量が若干増えていることも確認でき、膝OAの疾患修飾薬になる可能性が示唆された。

レジニアスはP1結果を受け、プロジェンザの膝OAを適応症としたP2を日本と米国で実施することを計画している。日本では昨年12月に旭硝子にプロジェンザの独占製造権を供与、旭硝子が日本でGMP治験薬を製造するほか、その費用をすべて負担することが決まっている。旭硝子はプロジェンザの製造受託を通じて、再生医療分野で受託製造の実績を積み上げていく方針。

レジニアスはプロジェンザの日本における独占開発・販売権の導出先を探し、相手先企業を通じ日本でP2の実施を目指す。日本では条件・期限付きの早期承認制度の活用を視野に入れている。ジョン・マーティンCEOはプロジェンザの日本での導出について「豪州P1で疾患修飾作用が一部示され、多くの企業が関心を寄せている。今年内には膝OAに関する基本合意書の締結を目指したい」としている。

プロジェンザについては、膝OAのほかに神経因性疼痛を適応症とした前臨床試験も進行中。同試験で良好な結果が得られれば、膝OAと同様に豪州でP1、その後に日米でのP2という開発スキームを検討している。

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