典晶生物获得珐博进生物合成角膜技术及重组 III 型人胶原蛋白平台独占许可权

典晶生物

- *获重组人胶原蛋白生物合成角膜独家全球开发和商业化权利*
- *临床阶段产品有望成为首个获得批准的生物合成人角膜*
- *生物合成角膜旨在解决全球治疗角膜致盲所需的角膜移植物的巨大未满足需求*
- *Edward Holland 医学博士成为典晶生物科学咨询委员会新成员*

中国苏州，美国旧金山，2021 年 7 月 19 日--典晶生物医药科技（苏州）有限公司 (简称典晶生物) 是一家专注于眼科的生物技术公司，总部位于中国苏州，在美国加利福尼亚州旧金山湾区设有子公司。典晶生物今天宣布从 FibroGen, Inc. (简称珐博进;纳斯达克股票代码：FGEN）获得了对源自重组 III 型人胶原蛋白、目前正处于研发阶段的生物合成角膜进行开发和商业化的全球独占许可权，用于治疗角膜致盲患者。

典晶生物董事长兼首席执行官张金忠博士表示：“我们非常高兴将这项创新技术首先引入中国市场，以满足对人供体角膜替代品的巨大医疗需求。据估计，中国每年出现超过十万例角膜致盲病例，原因是外伤或感染造成的角膜瘢痕，这类病例均可通过手术植入生物工程角膜治疗。中国目前的治疗方法包括人供体角膜移植或使用从转基因猪身上采集的角膜组织。然而，人供体角膜严重短缺，猪角膜存在光学透明度和耐久性不足的问题，这两种方法都需要额外的免疫抑制药物来防止移植排斥。人 III 型胶原是一种存在于正常人角膜中的关键结构蛋白。利用人 III 型胶原制成的生物合成角膜光学透明，可替代上述治疗方法，并无需使用免疫抑制药物。”

根据协议，典晶生物将向珐博进支付 800 万美元的预付款，珐博进还可在生物合成角膜项目未来达到生产、临床、注册和商业里程碑后获得总数高达 6400 万美元的付款，对于利用重组 III 型人胶原蛋白生产的首个非生物合成角膜的产品，珐博进还可获得高达 3600 万美元的商业里程碑付款。另外，珐博进还将有资格获得基于全球净销售额的特许权使用费。

典晶生物同时宣布 Edward Holland 博士成为典晶生物科学咨询委员会新成员。首席医学官 Charles Semba 博士表示："我们很高兴 Edward Holland 博士成为我们科学咨询委员会的新成员。Holland 博士现任美国辛辛那提大学眼科教授和辛辛那提眼科研究所角膜服务中心主任，曾任美国眼库协会主席。他是国际公认的角膜移植手术和眼角膜疾病专家。在过去三十年中，他多次到中国传授角膜移植技术。他的加入会对生物合成角膜项目的顺利实施起到至关重要的作用。"

Holland 博士指出：“生物合成角膜组织替代产品在全球的充足供应有望在很大程度上改变数百万生活在角膜来源匮乏地区的、没有机会通过接受角膜移植恢复视力的患者的命运。”

珐博进首席执行官 Enrique Conterno 表示：“我们很高兴能与典晶生物达成协议，将这项技术许可给这个经验丰富的眼科产品开发团队。此项交易将使珐博进能够专注于癌症、自身免疫和纤维化疾病、以及贫血的核心领域内新一代生物药物疗法的开发。”

关于典晶生物生物合成角膜项目

典晶生物的生物合成角膜 (EB-301) 是一种进入临床阶段的角膜基质替代品，将在中国市场首先开发。EB-301 属于三类医疗器械，预计于 2022 年下半年开始注册临床研究以确认其安全性和有效性。该角膜产品目前在欧洲已植入 10 名患者眼中并已随访四年，该产品显示出优异的生物相容性和保持光学透明，及在不使用免疫抑制药物的情况下，可以明显改善视力 (Fagerholm et al, Biomaterials, 35 (2014): 2420-2427)。

关于中国角膜盲

据世界卫生组织报道，角膜疾病是全球致盲的主要原因之一。全世界范围进行了大约十八万例旨在恢复视力的角膜移植手术，其中近四分之一是在美国进行的。中国是世界上人口最多的发展中国家，角膜疾病是致盲的第二大原因，估计有两、三百万患者至少有一只眼睛是角膜疾病致盲。然而，由于人供体角膜的稀缺，中国每年仅能进行约五千至九千例角膜移植手术。中国自 2015 年以来可使用猪角膜异种移植物，但光学透明度欠佳和继发性免疫并发症（例如：角膜植片溶解和排斥）的技术问题仍然存在。中国市场存在着寻求合适的角膜基质组织替代品的巨大医疗需求以满足人供体角膜和猪异种移植物替代品的短缺。

关于典晶生物

典晶生物（Eluminex Biosciences）是一家私有的、进入临床阶段的生物技术公司，专注于创新产品在全球的开发和商业化，以满足眼科疾病治疗和管理方面未满足的医疗需求。典晶生物致力于开发 first-in-class、best-in-class 眼科产品，旨在减少眼科疾病对患者视力的威胁并由此带来的生活不便。除了生物合成角膜（EB-301），典晶生物还正致力于研发一系列针对视网膜疾病（EB-101、EB-102、EB-105 和 EB-107）的下一代生物疗法，包括与年龄相关的黄斑变性、黄

斑水肿和糖尿病视网膜病变。这些产品线均为典晶生物独立拥有和开发。典晶生物全球总部和研发中心位于中国苏州生物医药产业园，美国子公司位于加利福尼亚州的旧金山湾区。典晶生物获得了三个顶级的风险基金的支持：礼来亚洲基金、高瓴创投和泉创资本。如需了解更多信息，请访问 www.eluminexbio.com。

关于珐博进

美国珐博进公司是一家致力于发现、开发和商业化首创（first-in-class）疗法产品管线的生物制药公司。公司将其在低氧诱导因子（HIF）和结缔组织生长因子（CTGF）生物学方面的开创性专业知识，用于开发针对未被满足的治疗需求的创新药物。公司目前正在开发和商业化一种口服小分子 HIF 脯氨酰羟化酶抑制剂 roxadustat（罗沙司他），用于治疗慢性肾病（CKD）相关的贫血。罗沙司他用于治疗骨髓增生异常综合征（MDS）相关贫血和化疗诱导性贫血（CIA）的临床开发也正在进行中。Pamrevlumab 是一种抗 CTGF 的全人源单克隆抗体，其用于治疗局部晚期不可切除胰腺癌（LAPC）、杜氏肌营养不良症（DMD）和特发性肺纤维化（IPF）的临床开发正在进行中。更多信息，请访问：www.fibrogen.com。

珐博进前瞻性声明

本新闻稿包含有关我们战略、未来计划和前景的前瞻性声明，包括有关公司受上述交易约束的候选产品的声明、候选产品的潜在安全性和有效性概况、其商业前景以及此类产品可能使用的适应症的发病率与患病率以及现有治疗方法这些前瞻性声明包括但不限于关于我们的计划、目标、陈述和观点的声明且非历史事实，通常通过使用诸如"可能"、"将"、"应该"、"正在进行"、"可能"、"预期"、"计划"、"预计"、"相信"、"估计"、"预测"、"潜在"、"继续"和类似术语的使用来识别，尽管某些前瞻性声明有不同的表达方式。我们的实际结果可能与这些前瞻性声明中指出的结果存在重大差异，这是因为与各种项目的持续进展和时间相关的风险和不确定性，包括正在进行的和未来可能开展的临床试验的入组和结果，以及我们向美国证券交易委员会（SEC）提交的截至 2020 年 12 月 31 日财年 10-K 表格年度报告以及截至 2021 年 3 月 31 日的 10-Q 表格季度报告中阐述的其他事项，包括其中的风险因素。我们提醒投资者不要过度依赖这些前瞻性声明，这些声明仅在本新闻稿发布之日有效。除非法律要求，我们没有义务更新本新闻稿中的任何前瞻性声明。

Eluminex Biosciences Exclusively Licenses FibroGen's Biosynthetic Cornea Technology and Recombinant Collagen III Platform

- *Exclusive Global Development and Commercialization Rights for Recombinant Human Collagen-Based Biosynthetic Cornea*
- *Clinical Stage Asset Has Potential for First Approved Biosynthetic Human Cornea*
- *Biosynthetic Cornea Designed to Address Significant Unmet Need in Global Demand for Corneal Grafts for the Treatment of Corneal Blindness*
- *Edward Holland, MD, Joins Eluminex's Scientific Advisory Board*

SUZHOU, China and SAN FRANCISCO, July 19, 2021 (GLOBE NEWSWIRE) -- Eluminex Biosciences (Suzhou) Limited (Eluminex), an ophthalmology-focused biotechnology company headquartered in Suzhou, China with a US-subsidiary office in San Francisco Bay Area, California, announced today that it has exclusively licensed global rights for the development and commercialization of an investigational biosynthetic cornea derived from recombinant human collagen Type III intended to treat patients with corneal blindness, from FibroGen, Inc. (FibroGen; NASDAQ: FGEN).

"We are extremely excited to bring this novel technology initially to the China market to help meet a large unmet medical need for an alternative to human donor cornea tissue," commented Dr. Jinzhong ("JZ") Zhang, Chairman and CEO of Eluminex. "Over 100,000 cases of corneal blindness occur each year in China due to scarring from traumatic injury or infection that could be treated with a surgically implanted bioengineered cornea. Typical treatments in China

include human donor corneal transplantation or use of corneal tissue harvested from genetically modified pigs. There is a significant shortage of human donor tissue and porcine corneas have issues with a lack of optical clarity and durability, however, and both methods require the need for additional immunosuppressive medications to prevent graft rejection. The biosynthetic cornea, that is optically clear, offers an alternative using human Type III collagen, a key structural protein that is found in normal human corneas and therefore does not require immunosuppressive medications."

Under the terms of the agreement, Eluminex will make an $8 million upfront payment to FibroGen. In addition, FibroGen may receive up to a total of $64 million in future manufacturing, clinical, regulatory, and commercial milestone payments for the biosynthetic cornea program, as well as $36 million in commercial milestones for the first recombinant collagen III product that is not the biosynthetic cornea. FibroGen will also be eligible to receive royalties based upon worldwide net sales.

Eluminex also announced that Edward Holland, M.D., has joined the company's Scientific Advisory Board (SAB). Charles Semba, M.D. and Chief Medical Officer of Eluminex commented, "We are excited to introduce Dr. Edward Holland, Professor of Ophthalmology at the University of Cincinnati and Director of the Cornea Service at the Cincinnati Eye Institute and past Chairman of the Eye Bank Association of America, as the newest member of our SAB. He is an internationally recognized expert in corneal allograft surgery and ocular surface disease. Additionally, over the past three decades, he has taught and lectured in China regarding corneal transplant techniques and will provide us critical insights into our biosynthetic cornea program."

"The possibility for an abundant global supply of a biosynthetic human corneal tissue substitute has real potential to transform the lives of the hundreds of thousands of patients around the world in regions where corneal donations are

scarce and who otherwise are unlikely to receive a sight-saving corneal transplant," said Dr. Holland.

"We are pleased to enter into this agreement with Eluminex and license this technology to a seasoned ophthalmology team," said Enrique Conterno, CEO of FibroGen. "This transaction enables FibroGen to focus on development of next generation biopharmaceutical therapies in our core areas of cancer, autoimmune and fibrotic diseases, and anemia."

About the Eluminex Biosynthetic Cornea Program

The Eluminex biosynthetic cornea (EB-301) is a clinical stage corneal stromal substitute that will be initially developed for the China market. EB-301 is regulated as a Class III medical device and is anticipated to enter a clinical market authorization registration study in China in 2H 2022 to confirm its safety and effectiveness. The corneal device has been implanted in 10 patients in Europe with 4 years of follow-up and has demonstrated excellent biocompatibility, maintenance of optical clarity, and significantly improved visual acuity without immunosuppression. (Fagerholm et al, Biomaterials, 35 (2014): 2420-2427).

About Corneal Blindness in China

According to the World Health Organization, corneal diseases are one of the leading causes of blindness globally. Approximately 180,000 sight-restoring corneal transplantations are performed worldwide in which nearly a quarter are conducted in the United States. China is the largest most populous developing country in the world and corneal diseases are the second leading cause of blindness with an estimated 2-3 million patients with corneal blindness in at least one eye. However, due to the scarcity of donor corneas, only approximately 5000 to 9000 corneal transplants are conducted in China each year. Corneal porcine xenografts have been available in China since 2015 but technical issues remain with the lack of optical clarity and secondary immunologic complications (eg, graft dissolution and graft rejection). An unmet need exists for a suitable corneal

stromal tissue replacement as an alternative to the shortage of donated human cornea and an alternative to porcine xenografts.

About Eluminex Biosciences

Eluminex Biosciences is a privately-held clinical-stage biotechnology company focused on both global and regional development and commercialization of innovative therapeutics to fulfill unmet medical needs in the treatment and management of ophthalmic diseases. Eluminex is devoted towards innovating the next generation of first-in-class or best-in-class ocular therapeutics for vision-threatening or lifestyle-limiting ocular diseases. In addition to the biosynthetic cornea (EB-301), Eluminex has developed a pipeline of next generation protein therapeutics for retinal diseases (EB-101, EB-102, EB-105, and EB-107) including age-related macular degeneration, macular edema, and diabetic retinopathy; these assets are wholly owned and developed by Eluminex. The Eluminex global headquarters and research and development center are located in Suzhou BioBay Industrial Park, China with a US-subsidiary located in the San Francisco Bay Area. Eluminex is supported by three premiere global life science venture funds: Lilly Asia Ventures, Hill House Capital, and Quan Capital. For more information, please visit www.eluminexbio.com.

About FibroGen

FibroGen, Inc. is a biopharmaceutical company committed to discovering, developing, and commercializing a pipeline of first-in-class therapeutics. The Company applies its pioneering expertise in hypoxia-inducible factor (HIF) and connective tissue growth factor (CTGF) biology to advance innovative medicines for the treatment of unmet needs. The Company is currently developing and commercializing roxadustat, an oral small molecule inhibitor of HIF prolyl hydroxylase activity, for anemia associated with chronic kidney disease (CKD). Roxadustat is also in clinical development for anemia associated with myelodysplastic syndromes (MDS) and for chemotherapy-induced anemia (CIA). Pamrevlumab, an anti-CTGF human monoclonal antibody, is in clinical development for the treatment of locally advanced unresectable pancreatic

cancer (LAPC), Duchenne muscular dystrophy (DMD), and idiopathic pulmonary fibrosis (IPF). For more information, please visit www.fibrogen.com.

Forward-Looking Statements of FibroGen

This release contains forward-looking statements regarding our strategy, future plans and prospects, including statements regarding the company's product candidates subject to the transaction described above, the potential safety and efficacy profile of the product candidates, their commercial prospects and the incidence and prevalence of possible indications of use for such products and existing treatments. These forward-looking statements include, but are not limited to, statements about our plans, objectives, representations and contentions and are not historical facts and typically are identified by use of terms such as "may," "will", "should," "on track," "could," "expect," "plan," "anticipate," "believe," "estimate," "predict," "potential," "continue" and similar, although some forward-looking statements are expressed differently. Our actual results may differ materially from those indicated in these forward-looking statements due to risks and uncertainties related to the continued progress and timing of our various programs, including the enrollment and results from ongoing and potential future clinical trials, and other matters that are described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2020 and our Quarterly Report on Form 10-Q for quarter ended March 31, 2021 filed with the Securities and Exchange Commission (SEC), including the risk factors set forth therein. Investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this release, and we undertake no obligation to update any forward-looking statement in this press release, except as required by law.