Eluminex Announces Completion of Enrollment in Part A of the CLARITY Study

A Registrational Clinical Trial Evaluating a Human Recombinant Collagen-derived Biosynthetic Cornea

Initial Part A results to be presented at the upcoming American Society of Cataract and Refractive Surgery Annual Meeting

EB-301 has the potential to be world's first approved rhCIII biosynthetic corneal implant for the treatment of corneal blindness

Suzhou, China, February 14, 2023 / San Francisco, USA (PR Newswire) — Eluminex Biosciences today announced the completion of clinical enrollment in Part A (N=5) of a two-part pivotal study (CLARITY) evaluating a novel EB-301 biosynthetic cornea being conducted in China. The EB-301 investigational corneal implant is manufactured from recombinant human Type III collagen (rhCIII) and is intended to treat corneal blindness secondary to stromal lesions amenable to anterior lamellar keratoplasty (ALK) surgery.

The CLARITY study is a registrational study being conducted in mainland China (Jiangsu Medical Product Agency, 20220171) with the anticipation of eventual marketing registration in the Greater China area. The study is a single arm, open label study being conducted at more than a dozen clinical sites in mainland China. The study consists of two parts. Part A is initial safety and feasibility and intended to evaluate at least 5 subjects. Part B is safety and effectiveness that will enroll up to 80 subjects. Enrolled subjects will be followed for 12 months with routine scheduled visits to assess safety and visual acuity outcomes. Details of the EB-301 implant and summary of initial Part A clinical results will be presented at the American Society of Cataract and Refractive Surgery, May 8, 2023, in San Diego, California.

The first enrolled patient in the CLARITY study was treated by Professor Mingchang Zhang, MD, Chief of Corneal Surgery at Wuhan Union Hospital, Wuhan, China in January 2023. The patient was blind in the study eye due to prior foreign body trauma. The operative procedure was successful without any observed complications. Post-operatively, the patient has near normal vision and further improvements are anticipated. "I am pleased with the progress of her recovery thus far. I am hopeful that this new technology will bring restoration of vision to the many patients in China and around the world who are not able to receive ready access to human corneal transplants," said Dr. Zhang.

"This landmark study represents the only biosynthetic corneal program in late-stage clinical development anywhere in the world," said Charles Semba, MD, Chief Medical Officer of Eluminex. "Corneal blindness is a leading cause of vision loss globally. There are an estimated 2 million patients in China in need of corneal transplantation but only 5000 to 8000 cases are performed each year due to

lack of availability of corneal allografts. Our hope is to bring a new alternative to patients in China and beyond, that is proven safe and effective in restoring vision" commented Semba.

About EB-301

EB-301 is a novel clinical stage first-in-class biosynthetic cornea derived from Type III recombinant human collagen and is in late-stage development initially for the China market. Eluminex Biosciences obtained the exclusive global license for the manufacturing, development, and commercialization of EB-301 from FibroGen (San Francisco, CA). EB-301 is intended for the treatment of visual acuity deficits associated with corneal blindness due to stable, non-infectious stromal lesions amenable to anterior lamellar keratoplasty (ALK) as an alternative to cadaveric human donor cornea. The implant is regulated as a Class III investigational medical device. EB-301 has several potential advantages over currently available porcine corneal implants including improved corneal clarity, no need for immunosuppressants, and serve as a tissue scaffold to allow ingrowth of surrounding stromal and epithelial tissue. Prior single-site investigator-initiated clinical studies have shown encouraging long term (> 4 years) durability with improved visual acuity and no corneal melt.

About Eluminex Biosciences

Founded in February 2020, Eluminex Biosciences is a privately held global biotechnology company focusing on ophthalmic diseases and recombinant human collagen technology with its main headquarters, research/development, and manufacturing center located in Suzhou Industrial Park BioBAY and a US operational campus located in South San Francisco, California. Under the leadership of a seasoned management team, Eluminex aims to build an innovative and sustainable pipeline to address the unmet clinical needs for ophthalmic diseases and other indications to benefit patients in China and globally. For more information, visit www.eluminexbio.com.

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典晶生物完成生物合成角膜临床试验第一部分病人入组

- EB-301 有望成为全球首个应用重组 III 型人胶原蛋白制成的生物合成角膜治疗角膜盲的产品

2023 年 2 月 20 日， 中国苏州/美国旧金山 - 典晶生物医药科技（苏州）有限公司（典晶生物）今天宣布完成注册临床研究 CLARITY 第一部分 6 位志愿者入组并成功接受生物合成角膜移植手术。CLARITY 临床试验旨在评估由重组 III 型人胶原蛋白制成的生物合成角膜（EB-301）治疗由基质病变引起且适合前板层角膜移植手术 (ALK) 的角膜盲。

CLARITY 研究是在中国大陆进行的一项注册临床研究（江苏省药品监督管理局注册号：20220171）。该研究是一项单臂、开放标签研究，正在十几个临床中心进行。该研究由两部分组成：第一部分是初始安全性和可行性评估，计划入组至少 5 名受试者。在接下来的第二部分将对安全性和有效性进行评估，将招募约 80 名受试者。受试者将被随访 12 个月，以进行安全性和视力改善等疗效终点的评估。北京同仁医院潘志强教授担任该临床研究的首席研究员。

CLARITY 临床研究首例患者的角膜移植手术由华中科技大学同济医学院附属协和医院张明昌教授团队于 2023 年 1 月 6 日完成。该患者由于 8 年前异物入眼导致外伤，右眼几近失明。手术很成功，目前没有观察到任何并发症。手术后的第四天，患者的视力恢复到 0.4。张教授表示 “我对她目前的康复进展感到非常满意，希望这项新技术能够为中国乃至世界各地因人供体角膜缺乏而无法进行角膜移植手术的众多患者带来视力恢复的希望。” 昆明医科大学第一附属医院张慧教授团队和南京市第一医院陈力迅教授团队共同参与了 CLARITY 第一部分的临床研究。

“这项研究是目前世界上唯一处于后期临床开发阶段的生物合成角膜项目，具有里程碑意义。” 典晶生物首席医学官 Charles Semba 博士说 “角膜盲是全球视力丧失的主要原因之一。中国有超过 400 万患者需要角膜移植，但由于缺乏人供体角膜，每年只能进行 5000 至 8000 例移植手术。我们希望为中国及其它地区的患者带来一种新的角膜替代疗法。”

关于 EB-301

EB-301 是一种创新的生物合成角膜，由在酵母细胞中合成的具有三股螺旋结构的全长重组 III 型人胶原蛋白制成，属于三类医疗器械，处于临床后期开发阶段，产品将首先面向中国市场。典晶生物从美国 FibroGen 公司获得了 EB-301 开发和商业化的全球独家许可。EB-301 旨在治疗由稳定的、非感染性基质病变引起的角膜失明，可作为人供体角膜的替代品，适用于前板层角膜移植手术 (ALK)。与目前市场上可用的角膜植入物相比，EB-301 具有几个潜在优势，包括更好的角膜透明度，不需要服用免疫抑制剂，以及作为组织支架诱导周围组织包括角膜上皮细胞向内生长。

关于典晶生物

典晶生物医药科技（苏州）有限公司成立于 2020 年 2 月，是一家专注于眼科疾病和重组人胶原蛋白技术的生物技术公司，其总部、研发和生产中心位于苏州工业园区 BioBAY，在美国旧金山湾区设有全球临床和注册中心。如需更多信息，请访问 www.eluminexbio.com。