Eluminex Biosciences Successfully Completes Its First Pre-IND Meeting with the United States Food and Drug Administration for a Multivalent Fc Fusion Protein (EB-101) for the Treatment of Neovascular Age-related Macular Degeneration

- EB-101 is a Novel Second Generation Angiogenic Inhibitor Targeting Multiple VEGF Family Ligands
- FDA Agrees with Proposed First-in-Human Phase 1/2a Study Design
- Investigational New Drug Application Filing Anticipated in 2023

SUZHOU, China and SAN FRANCISCO, CA, January 17, 2022 / 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 that it successfully completed the first pre-IND (Investigational New Drug) meeting with the U.S. Food and Drug Administration (FDA) on December 15, 2021, regarding the nonclinical and clinical development plan for EB-101, a recombinant human Fc fusion protein.

EB-101 is one of the leading investigational multivalent second-generation intravitreal agents in the Eluminex pipeline that are wholly developed and owned by Eluminex Biosciences for the treatment of neovascular age-related macular degeneration (nAMD) and other retinal vascular disorders. This first-in-class biological agent leverages state-of-the-art advances in protein engineering and is specifically designed to address the multifactorial etiology of angiogenesis beyond currently approved anti-VEGF therapies.

Eluminex has obtained alignment with FDA on the nonclinical and clinical development plan for EB-101 to support the IND application and initiation of a first-in-human (FIH) Phase 1/2a clinical trial for the treatment of nAMD in the adult population. FDA agreed with Eluminex proposed scope of the clinical FIH Phase 1/2a clinical trial in nAMD, including the study design, patient population, duration of treatment, and endpoints.

FDA also provided general guidance on clinical development expectations at the time of EB-101 Biologics License Application (BLA) submission.

According to FDA's pre-IND feedback/guidance, Eluminex Biosciences plans to file an IND for EB-101 to US FDA in 2023.

About Eluminex Biosciences

Eluminex Biosciences (Eluminex) 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. Eluminex has developed a pipeline of multivalent 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. In addition, Eluminex is currently developing the world's first recombinant human collagen-derived biosynthetic cornea (EB-301) for the treatment of corneal blindness.

The Eluminex global headquarters and research and development center are 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, Hillhouse Capital Management, and Quan Capital.

For more information, please visit www.eluminexbio.com.

About Age-related Macular Degeneration (AMD)

AMD is a leading cause of vision loss in people over the age of 50 in the industrialized world. Symptoms of AMD include blurred or distorted central vision and black spots (scotomas). There are two forms of AMD – dry and wet. Dry AMD accounts for nearly 85 to 90% of all cases and represents the earliest stages of AMD and is caused by fatty deposits (drusen) in the central retina, called the macula, and often not associated with any vision loss.

About 10 to 15% of patients with dry AMD progress to wet AMD. Wet AMD occurs in later stages of AMD where new blood vessels (neovascular) abnormally form in the back of the retina (choroid) – a process referred to as angiogenesis. These neovascular blood vessels can leak fluid (edema) causing swelling of the retinal tissue and/or bleed abnormally. A potential consequence is the development of irreversible scar tissue and vision loss.

While wet AMD constitutes only 10-15% of all cases of AMD, it accounts for more than 90% of permanent vision-loss in patients with AMD. Risk factors include smoking, obesity, family history, and race. Despite the availability of

anti-VEGF drugs to treat nAMD, many patients have only partial response and require frequent injections. An unmet need exists for newer treatments that can improve efficacy and durability of response.

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典晶生物成功与美国 FDA 就 EB-101 项目召开 Pre-IND 会议

- EB-101 是新一代多靶点抗 VEGF 的融合蛋白，用于治疗 nAMD
- FDA 认可该项目首次人体临床试验（1/2a 期）的研究设计方案
- 该项目预计将在 2023 年进行 IND 申报

典晶生物于 2021 年 12 月 15 日成功与美国食品药品监督管理局（FDA）就一个治疗新生血管年龄相关性黄斑病变的项目召开 Pre-IND 会议。

EB-101 是典晶生物研发管线中领先的第二代多价玻璃体腔内注射药物，该分子由典晶生物自主开发，用于治疗新生血管年龄相关性黄斑病变（nAMD）和其它视网膜血管疾病。这种创新的生物制剂利用抗体工程的最新进展并针对当前抗 VEGF 疗法无法解决的异常血管增生的多生物学因素而专门设计。

典晶生物与 FDA 就 EB-101 的临床前和临床试验方案达成一致，包括临床研究设计、患者人群、疗程及试验终点，以支持该项目 IND 申请和启动首次人体（FIH）1/2a 期临床试验，首先用于治疗成人 nAMD。此外，FDA 也就 EB-101 项目未来提交生物制品许可申请（BLA）时的临床开发

预期给予了相关指导。根据 FDA 在 Pre-IND 会议上提供的反馈及指导，典晶生物计划在 2023 年就该项目提交 IND 申请。

关于年龄相关性黄斑病变（AMD）

年龄相关性黄斑病变（AMD）是工业化国家 50 岁以上人群视力丧失的主要原因。AMD 的症状包括中心视力模糊、扭曲和黑点（暗点）。AMD 有两种形式——干性和湿性。干性 AMD 占所有病例的近 85%至 90%，代表 AMD 的初期阶段，由视网膜中央（称为黄斑）中的脂肪沉积（玻璃疣）引起，通常不会严重影响视力。大约 10%至 15%的干性 AMD 患者会发展为湿性 AMD。湿性 AMD 发生在 AMD 的后期阶段，由异常血管在视网膜后部（脉络膜）增生所致，这一过程被称为新生血管。这些新生血管会引发出血或液体渗漏，导致视网膜下出血或视网膜组织肿胀。其潜在后果是发展为不可逆的疤痕组织和视力丧失。虽然湿性 AMD 仅占所有 AMD 病例的 10-15%，但它占 AMD 永久性视力丧失患者的 90%以上。其危险因素包括吸烟、肥胖、家族史和种族等。尽管目前市场上使用抗 VEGF 药物来治疗湿性 AMD，且需要频繁注射，但有部分患者收效甚微，目前市场上对能够提高疗效和效力持久性的新疗法的需求尚未得到满足。

关于典晶生物

典晶生物是一家处于临床阶段的生物技术公司，专注于创新疗法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需求。典晶生物致力于开发同类首个或者同类最优的眼科治疗方法，减少眼科疾病对患者视力的威胁和由此带来的生活不便。除了生物合成角膜项目，典晶生物目前正在研发一系列用于治疗视网膜疾病的下一代生物疗法。这些管线产品均为典晶生物全权拥有和独家开发。

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区，美国子公司位于加州旧金山湾区。典晶生物获得了三家顶级风险投资基金的支持：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。