

Tenacia Biopharmaceuticals and Golden Age Health Partner to Commercialize ZTALMY® for CDKL5 Deficiency Disorder in Mainland China

First-ever approved treatment for CDD in China now set for commercial launch through dedicated rare disease platform

SHANGHAI--(BUSINESS WIRE)-- **Tenacia Biopharmaceuticals (Shanghai) Co., Ltd.** ("Tenacia") and **GOLDEN AGE HEALTH (SHANGHAI) CO., LTD.**, a subsidiary of Golden Age Health Pte. Ltd. (collectively, "**GAH**") today announced a **Commercialization Agreement** granting GAH exclusive rights to commercialize **ZTALMY®** (泽元安), the first and as of now only approved treatment for **CDKL5 deficiency disorder (CDD)** in Mainland China.



ZTALMY® (ganaxolone oral suspension) was developed by Marinus and Tenacia obtains exclusive rights to develop and commercialize it in Greater China. In July 2024, the drug was approved by the National Medical Products Administration for treatment of seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD) in patients 2 years of age and older.

Tenacia has partnered with GAH to leverage its comprehensive patient-focused commercialization platform—encompassing disease awareness, diagnosis support, market access, and patient affordability programs—to ensure this therapy reaches the families affected by this devastating rare epilepsy.

"Bringing the first approved therapy for CDKL5 deficiency disorder to patients in China represents exactly the type of mission-critical work Golden Age Health was built for," said **Chao (Brook) Wu, Chief Executive Officer of Golden Age Health (Shanghai)**. "We are honored to partner with Tenacia to ensure that children and families affected by CDD can access this breakthrough treatment as quickly as possible."

Dr. Xiaoxiang Chen, Founder and CEO of Tenacia Biopharmaceuticals (Shanghai), said: "GAH's proven expertise in rare disease commercialization and their commitment to patient access make them the ideal partner to bring ZTALMY® to the patients who need it most in China. Together, we will work to maximize the impact of this important therapy."

About CDKL5 Deficiency Disorder

CDKL5 deficiency disorder (CDD) is a rare developmental epileptic encephalopathy caused by mutations in the CDKL5 gene. Patients typically experience early-onset, treatment-resistant seizures, profound developmental delays, and motor impairments. CDD is included in China's **National Rare Disease Catalog**, reflecting the urgent need for effective treatments for affected patients and their families.

About ZTALMY® (ganaxolone oral suspension)

ZTALMY® (ganaxolone oral suspension) is a neuroactive steroid GABA_A receptor positive allosteric modulator. The oral suspension formulation (110ml: 5.5g) is approved by China's NMPA for the treatment of seizures associated with CDKL5 deficiency disorder in patients 2 years of age and older. It represents the first therapy specially approved for this indication in China.

About Golden Age Health

Golden Age Health is a specialty pharmaceutical company dedicated to redefining patient access to medicine across China, Asia-Pacific and MEA. Headquartered in Singapore, GAH pairs data-driven market-access expertise with deep medical-affairs and RWE capabilities to bring high-impact therapies to underserved populations.

About Tenacia Biopharmaceuticals

Founded in 2022 by Bain Capital, Tenacia is a commercial-stage biopharmaceutical company dedicated to developing innovative therapeutics for patients with underserved neurological disorders. Tenacia's seasoned management team brings decades of drug development experience from both MNCs and biotechs. Their deep understanding of complex disease biology and insights into unmet patient needs enable Tenacia to create a highly efficient neuroscience R&D platform with a proven track record of advancing novel therapies. Empowered by its founder and strategic investor, Bain Capital – through significant initial investment, long-term commitment and extensive life science network – Tenacia is poised to become a leading neuroscience company in China and deliver substantial value to shareholders while upholding an unwavering commitment to the patients.

Forward-Looking Statements

This release contains forward-looking statements, including expectations regarding clinical development, regulatory matters and commercial launches. These statements involve risks and uncertainties that may cause actual outcomes to differ materially.

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元羿生物携手金康诃医药科技，共同推进泽元安[®]（加那索龙口服混悬剂）在中国内地的商业化进程

专业化罕见病平台助力中国首个获批 **CDKL5 缺乏症** 疗法造福中国患者

2026 年 2 月 1 日 上海——元羿生物医药（上海）有限公司（Tenacia Biopharmaceuticals (Shanghai) Co., Ltd., 简称“元羿生物”）与金康诃医药科技(上海)有限公司 GOLDEN AGE HEALTH (SHANGHAI) CO.,LTD.及其母公司 Golden Age Health Pte. Ltd.（统称“GAH”）今日宣布签署商业化合作协议，授予 GAH 在中国内地独家商业化加那索龙口服混悬剂（泽元安[®]）的权利。该药物是中国首个且目前唯一获批用于治疗 **CDKL5 缺乏症（CDD）** 相关癫痫的疗法。



泽元安[®]（加那索龙口服混悬剂）由 **Marinus** 研发，元羿生物授权引进，拥有其在大中华区开发及商业化权益。2024 年 7 月该药获得国家药品监督管理局批准，用于治疗 2 岁及以上细胞周期蛋白依赖性激酶 5（**CDKL5**）缺乏症患者癫痫发作。为确保这一疗法惠及饱受该罕见癫痫困扰的家庭，元羿生物此次携手 **GAH**，借助其以患者为中心的综合商业化平台，涵盖疾病认知普及、诊断支持、市场准入及患者可负担性项目，全方位提升治疗可及性。

“将中国首个 **CDKL5 缺乏症** 获批疗法带给患者，正是金康诃医药科技成立以来致力于推进的核心使命，”金康诃医药科技（上海）首席执行官吴超（**Brook Wu**）表示，“我们很荣幸能与元羿生物合作，让更多饱受 **CDKL5 缺乏症** 疾病折磨的儿童和家庭能够尽快获益于这一突破性治疗。”

元羿生物创始人兼首席执行官陈小祥博士表示：“**GAH** 在罕见病商业化领域拥有成熟的专业能力，且始终致力于保障患者用药可及性，是将泽元安[®] 带给中国最需要的患者的理想合作伙伴。我们将携手共进，最大限度发挥这一重要疗法的价值。”

关于 **CDKL5 缺乏症（CDD）**

CDKL5 缺乏症（CDD） 是一种由 **CDKL5** 基因突变引起的罕见的发育性癫痫性脑病。患者通常表现为早发性、难治性癫痫发作，伴有严重的发育迟缓及运动功能障碍。**CDD** 已被纳入《中国罕见病目录》，反映出受影响患者及其家庭对有效治疗手段的迫切需求。

关于 泽元安[®]（加那索龙口服混悬剂）

泽元安[®]（加那索龙口服混悬剂）是一种神经活性类固醇，靶向 γ -氨基丁酸（GABA）A 型受体的正向变构调节剂。该口服混悬液剂型（110 毫升：5.5 克）已获得国家药品监督管理局批准，用于治疗 2 岁及以上 CDKL5 缺乏症相关的癫痫发作，是中国首个专门针对该适应症获批的疗法。

关于金康诃医药科技

金康诃医药科技是一家专注于中国、亚太地区及中东和非洲地区患者用药可及性的罕见病和特殊疾病创新疗法制药公司。公司总部位于新加坡，凭借专业的市场准入和推广能力，结合深厚的医学事务及真实世界证据（RWE）研究实力，为医疗需求未被满足的人群带来高质量创新疗法。

关于元羿生物

元羿生物成立于 2022 年，总部位于中国上海，是一家处于商业化阶段的、专注于神经科学领域的创新型生物制药公司。元羿生物由贝恩资本投资，携手兼具国际化背景以及深谙中国生物医药生态系统的资深专业团队共同创立，以患者需求为先，通过与全球生态伙伴的战略合作，汇聚神经科学领域的专业和实力，驱动前沿技术的转化，致力于为中国及全球的患者提供首创或者同类最佳的创新解决方案，全面提高患者及其家庭的生命质量。

前瞻性声明

本新闻稿包含前瞻性声明，包括对临床开发、监管事务及商业化上市的预期。这些声明涉及风险和不确定性，可能导致实际结果与预期存在重大差异。

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元羿生物（Tenacia Biopharmaceuticals）

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