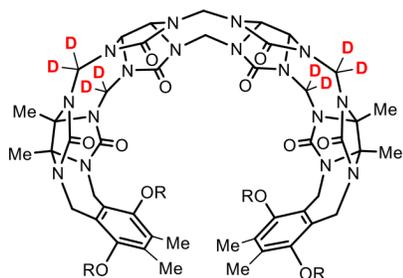


FY3452

Development of the First Universal Antagonist That Rapidly Reverses All Nonpolarizing Neuromuscular Blocking Agents (NMBAs)



FY3452

FY3452 is a novel broad-spectrum and rapid-acting neuromuscular blocking agent (NMBA) antagonist candidate compound. It is designed to provide fast reversal of the three most widely used and commercially dominant neuromuscular blocking agents in clinical practice: cisatracurium besylate, rocuronium bromide, and vecuronium bromide.

• Indications

Rapidly reverse all three clinically used NMBAs:

- ✓ For cisatracurium: first in class
- ✓ For rocuronium: best in class
- ✓ For vecuronium: best in class

• Development and Advancement

- ✓ The first deuterated drug in anaesthesia
- ✓ De nova design based on supramolecular recognition principle
- ✓ 1st drug candidate for anaesthesia from academic organization.
- ✓ New antagonism mechanism: supramolecular interpenetration (rotaxation)
- ✓ PreIND advance: finish preparation, scaling and process, analysis method establishment, quality control in May
- ✓ Scheduled to conduct ADMET and activity assessment in vivo from July

• Key facts on clinical neuromuscular blockade and antagonism:

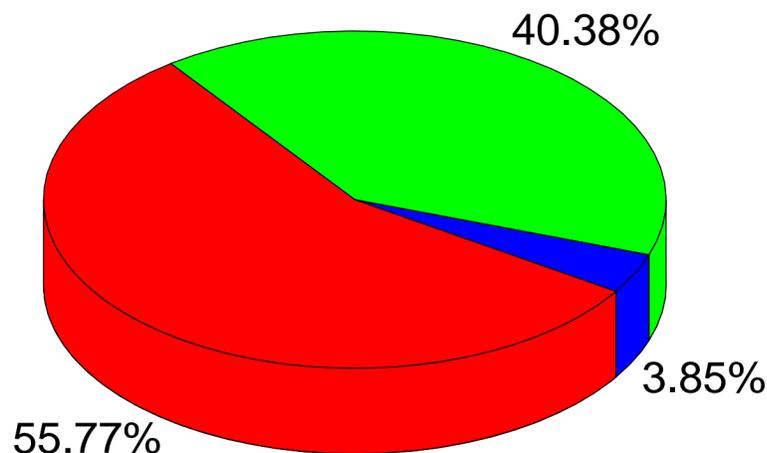
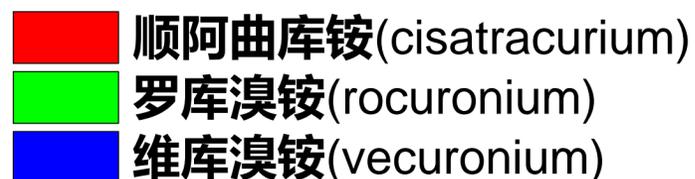
- ✓ Annual 82 million of surgical operations in China, 300+ million of operations globally.
- ✓ 5-7% annual increase of the number of surgical operations.
- ✓ Approximately 56% of operations face NMBA residual.
- ✓ Clinically there are no universal antagonists for NMBAs.

• Market Potential

- ✓ CNY 2.5 billion in China
- ✓ CNY 15 billion globally

Vs: Sugammadex

- USD 1.7 billion globally (2024)
- Sugammadex (approved by FDA in 2015): rapidly reverse rocuronium and vecuronium, but not cisatracurium.



Market Share in China (2024)



Dr. Zhanting Li, Co-founder
Suzhou Shinewin
Pharmaceuticals Co., Ltd.

Inventor of FY3452
Leading scientist in
supramolecular drug
development
Professor, Shanghai Institute
of Organic Chemistry,
Chinese Academy of
Sciences



Dr. Gang Zhao, CEO/Co-
founder
Suzhou Shinewin
Pharmaceuticals Co., Ltd.

• Patent Application and Intellectual Property

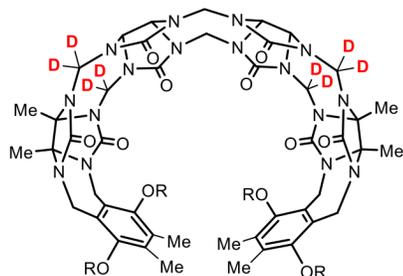
- ✓ International Patent Application No. PCT/CN2024/115569
- ✓ Chinese Patent Application No: 202311180470.6 (open date: 2025.03.14)
- ✓ European (EP) Patent Application No: 24864468.4
- ✓ US Patent Application: to be submitted soon (final stage of submission)
- ✓ Suzhou Shinewin Pharmaceutical had acquired exclusive right of the patent from SIOC through a milestone transfer agreement.

• Publications on World Top Journals:

- ✓ Z.-T. Li *et al.*, *J. Med. Chem.* 2025, 68, 7031–7043.
- ✓ Z.-T. Li *et al.*, *J. Med. Chem.* 2024, 67, 2176–2187.
- ✓ Z.-T. Li *et al.*, *J. Med. Chem.* 2022, 65, 16893–16901.
- ✓ Z.-T. Li *et al.*, *Chem. Sci.* 2022, 13, 9243–9248.

FY3452

全球第一款快速拮抗神经肌肉阻滞药物 (NMBA) 的通用拮抗剂



FY3452

FY3452是一款新型广谱性和快速活性的肌松药拮抗剂候选化合物，将主要针对目前临床上使用最为广泛使用，市场占比也是最大的三类肌松药（顺苯磺阿曲库铵、罗库溴铵和维库溴铵），进行快速拮抗。

适应症

快速逆转所有临床中时效非去极化性肌松剂：

- ✓ 针对顺阿曲库铵：first in class
- ✓ 针对罗库溴铵：best in class
- ✓ 针对维库溴铵：best in class

技术先进性

- ✓ 第一个麻醉学领域氘代药物
- ✓ 基于超分子识别机制的原创药物
- ✓ 源自学术机构的第一个麻醉学领域候选药物
- ✓ 基于新拮抗机制的研发：超分子互穿（轮烷化）
- ✓ 临床前研究进展：5月份完成制备放大与处理工艺、分析质检方法、质量控制。7月开始吸收、分布、代谢、排泄、毒性、毒理及药效评价

临床全麻手术肌松和拮抗关键事实：

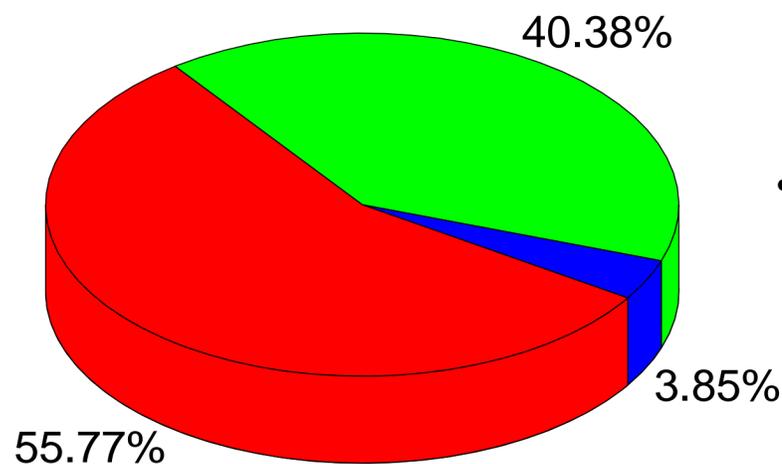
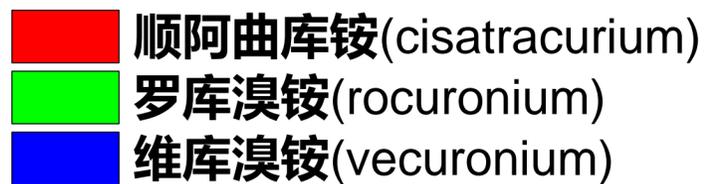
- ✓ 中国每年有超过8200万例全麻手术，全球每年有超过3亿例全麻手术
- ✓ 全麻手术数量每年递增5-7%
- ✓ 所有全麻手术都需要肌肉松弛
- ✓ 大约56%的手术肌肉松弛药物存在残留，临床麻醉界广泛共识需要拮抗
- ✓ 目前临床上没有通用快速拮抗剂

市场潜力

- ✓ 中国：25亿人民币
- ✓ 全球：150亿人民币

对比：舒更葡糖钠

- 2024年全球销售额：>17亿美元
- 舒更葡糖钠2015年被FDA批准拮抗罗库溴铵和维库溴铵，但对顺阿曲库铵无效。



Market Share in China (2024)



黎占亭博士, Co-founder
苏州深威药物有限公司

FY3452发明人
世界领先的超分子药物化学家
中国科学院上海有机化学研究所研究员



赵刚博士, CEO/ co-founder
苏州深威药物有限公司

专利申请与知识产权

- ✓ 国际专利申请号：PCT/CN2024/115569
- ✓ 中国专利申请号：202311180470.6 (公开日期：2025.03.14)
- ✓ 欧洲专利申请号：24864468.4
- ✓ 美国专利申请：近期完成申请流程
- ✓ 苏州深威药物有限公司通过里程碑转让协议获得FY3452全球研发与销售独占权

研究成果在国际顶级药物化学刊物发表：

- ✓ Z.-T. Li *et al.*, *J. Med. Chem.* 2025, 68, 7031–7043.
- ✓ Z.-T. Li *et al.*, *J. Med. Chem.* 2024, 67, 2176–2187.
- ✓ Z.-T. Li *et al.*, *J. Med. Chem.* 2022, 65, 16893–16901.
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