

FOSUNKite

——复星凯特生物——

专注治愈 点亮人生

2024年国家医保药品目录调整
拟谈判新增药品报送材料

通用名：阿基仑赛注射液

商品名：奕凯达®

复星凯特生物科技有限公司

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基本信息：目前中国首个且唯一获批上市治疗2L及以上LBCL的CAR-T产品

通用名	阿基仑赛注射液 ¹
注册规格	约为 68mL/袋 ，目标剂量为 2.0×10^6 个抗CD19 CAR-T细胞/kg体重
中国大陆首次上市时间	2021年6月22日
目前大陆地区同通用名药品的情况	无其他同通用名药品
全球首个上市国家地区及上市时间	2017年10月18日，美国
是否为OTC药品	否
参照药品建议	无 ，本品为LBCL治疗领域首个获批的治疗淋巴瘤的CAR-T产品，暂无临床广泛应用的医保目录中细胞治疗产品

适应症

本品为经基因修饰的靶向人 CD19 的嵌合抗原受体自体T (CAR-T) 细胞，用于治疗：

- 1、**一线免疫化疗无效或在一线免疫化疗后 12 个月内复发的成人B 细胞淋巴瘤 (r/r LBCL)**。本适应症为附条件批准上市，上市后将提供更多的有效性和安全性数据。
- 2、**既往接受二线或以上系统性治疗后复发或难治性大 B 细胞淋巴瘤成人患者，包括弥漫性大 B 细胞淋巴瘤 (DLBCL) 非特指型 (NOS)，原发纵隔大 B 细胞淋巴瘤 (PMBCL)、高级别 B 细胞淋巴瘤和滤泡性淋巴瘤转化的 DLBCL。**

用法用量

请在有血液肿瘤治疗经验的医生指导和监督下使用本品治疗。

- 确认患者身份与产品袋标签上的患者信息相符。
- 37°C水浴复融本品。
- 输注前后用生理盐水冲管。
- 通过重力或蠕动泵在30分钟内将本品产品袋内所有内容物单次静脉输入患者体内。
- 本品体积约为68 mL/袋，目标剂量为 2.0×10^6 个抗CD19 CAR-T细胞/kg体重（可接受范围： $1.5 \times 10^6 \sim 2.0 \times 10^6$ 个抗CD19 CAR-T细胞/kg体重），最高为 2.0×10^8 个抗CD19 CAR-T细胞/剂量。
- 本品输注期间，轻轻晃动产品袋，以防止细胞聚集。

基本信息：阿基仑赛注射液能够帮助更多患者提高治疗缓解率， 延长生存年限，实现潜在治愈

疾病基本情况

LBCL是我国常见的血液系统恶性肿瘤，危害性大、死亡率高：

- NHL仍然是全球和亚洲国家面临的重大挑战¹，中国发病率逐年上升，疾病负担逐年加重^{2,3}；
- LBCL是NHL最常见的亚型⁴，中国DLBCL占有NHL的45.8%⁵，估算每年新发DLBCL超过4万例；
- 尽管国内LBCL一线治疗与国外看齐(R-CHOP标准方案)，仍有30%~40%的患者难治和复发(每年新发超过13,000例)⁶，73%的患者经过二线治疗后再次发生了疾病进展⁷。

现有复发/难治LBCL常规治疗手段预后差、生命质量低、生存期短：

- REAL-TREND研究⁸显示中国接受过二线以上治疗的复发或难治性DLBCL患者的生存期很短——中位总生存期**5.9**个月，2年生存率**16%**，生活质量差；
- 挽救性化疗+ASCT为LBCL二线标准治疗方案⁹，但能真正进行正规治疗并从移植中有长期生存获益的患者比例非常有限¹⁰⁻¹³；
- 中国每年新发的4万例DLBCL中约30%无法通过一线治疗治愈（约13,000例），而国内可以作为标准治疗的自体移植用于NHL的不到2000人（2723例的41%）¹⁴，说明LBCL一线治疗后难治或复发的患者存在迫切巨大的未满足的治疗需求。

阿基仑赛注射液治疗优势

- 阿基仑赛注射液能够给患者带来持久的缓解，显著改善患者长期生存；

	三线		二线
	ZUMA-1 ¹⁵	中国RWS ¹⁶	ZUMA-7 ¹⁷
最佳总缓解率 (bORR)	83%	83%	83%
最佳完全缓解率 (bCR)	58%	63%	65%
OS率	43% (5年)	80% (1年)	55% (4年)

- 阿基仑赛注射液帮助实现患者治愈的可能，5年生存的患者中92%不需要额外的抗癌治疗¹⁵；
- 阿基仑赛注射液是**一次性治疗使用**的创新细胞疗法药物，能够减轻患者负担（反复住院，生产力损失，节约医疗资源），**提高患者生活质量。**

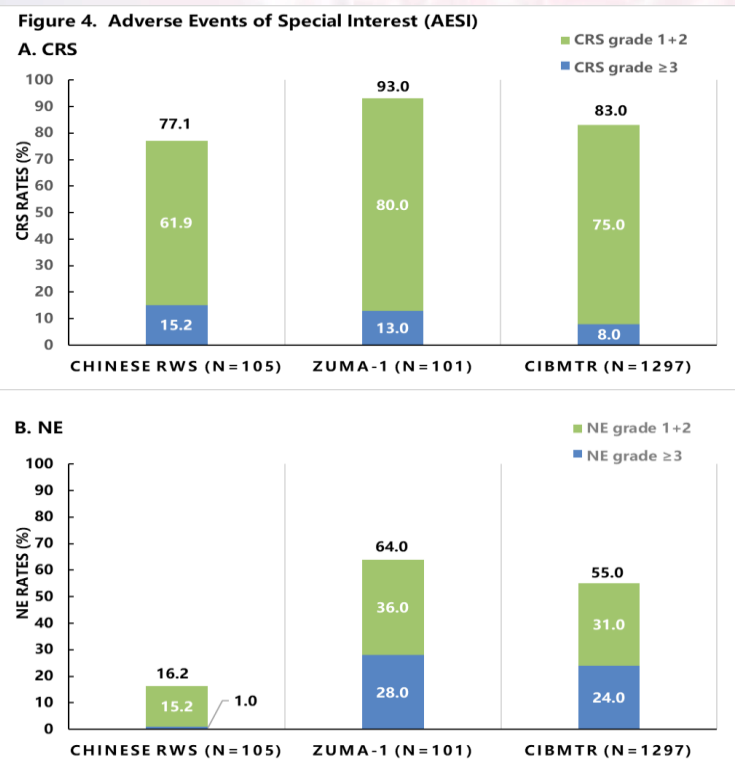
FOSUNKite 安全性：阿基仑赛注射液整体安全性良好，不良事件可控易管理

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- 在中国患者中，没有发现新的治疗相关不良事件¹。
- 最常见≥3级TEAE为：白细胞计数下降（87.6%），中性粒细胞减少（82.9%）和淋巴细胞计数降低（73.3%）
- 77.1%受试者发生任意级别CRS，其中**≥3级CRS发生率为15.2%**，与ZUMA-1和CIBMTR相当
- 16.2%受试者发生任意级别NE，其中**≥3级NE发生率为1.0%**，低于ZUMA-1和CIBMTR
- 在中国患者中，**皮质醇激素的早期小剂量干预**，可能是较低NE发生率的原因之一
- 随着CAR-T细胞疗法的应用，**不良反应管理和CAR-T全程管理规范落地和实施**，细胞治疗不良事件更可控、更易管理

任意级别CRS发生	例数n (%)	81 (77.1%)
≥3级CRS发生	例数n (%)	16 (15.2%)
至CRS发生时间	中位数, 天	4.0
CRS持续天数	中位数, 天	10.0

任意级别NE发生	例数n (%)	17
≥3级NE发生	例数n (%)	1 (1.0%)
至NE发生时间 (天)	中位数, 天	8.0
NE持续天数 (天)	中位数, 天	6.0



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· 指南与共识 ·

CAR T 细胞治疗 NHL 毒副作用临床管理专家共识

中国研究型医院学会细胞治疗专委会

【摘要】嵌合抗原受体T细胞(Chimeric Antigen Receptor T Cell, CAR-T)细胞治疗淋巴瘤及实体瘤等恶性肿瘤的突破性进展，为淋巴瘤患者带来了新的治疗选择。然而，CAR-T细胞治疗在带来临床获益的同时，也伴随着一系列严重的毒副作用。因此，制定CAR-T细胞治疗的临床管理专家共识，对于规范CAR-T细胞治疗的临床管理，提高患者治疗的安全性和有效性具有重要意义。

【关键词】CAR-T细胞治疗；淋巴瘤；毒副作用；临床管理；专家共识

【中图分类号】R735.71；R735.72；R735.73；R735.74；R735.75；R735.76；R735.77；R735.78；R735.79；R735.80；R735.81；R735.82；R735.83；R735.84；R735.85；R735.86；R735.87；R735.88；R735.89；R735.90；R735.91；R735.92；R735.93；R735.94；R735.95；R735.96；R735.97；R735.98；R735.99；R736.00；R736.01；R736.02；R736.03；R736.04；R736.05；R736.06；R736.07；R736.08；R736.09；R736.10；R736.11；R736.12；R736.13；R736.14；R736.15；R736.16；R736.17；R736.18；R736.19；R736.20；R736.21；R736.22；R736.23；R736.24；R736.25；R736.26；R736.27；R736.28；R736.29；R736.30；R736.31；R736.32；R736.33；R736.34；R736.35；R736.36；R736.37；R736.38；R736.39；R736.40；R736.41；R736.42；R736.43；R736.44；R736.45；R736.46；R736.47；R736.48；R736.49；R736.50；R736.51；R736.52；R736.53；R736.54；R736.55；R736.56；R736.57；R736.58；R736.59；R736.60；R736.61；R736.62；R736.63；R736.64；R736.65；R736.66；R736.67；R736.68；R736.69；R736.70；R736.71；R736.72；R736.73；R736.74；R736.75；R736.76；R736.77；R736.78；R736.79；R736.80；R736.81；R736.82；R736.83；R736.84；R736.85；R736.86；R736.87；R736.88；R736.89；R736.90；R736.91；R736.92；R736.93；R736.94；R736.95；R736.96；R736.97；R736.98；R736.99；R737.00；R737.01；R737.02；R737.03；R737.04；R737.05；R737.06；R737.07；R737.08；R737.09；R737.10；R737.11；R737.12；R737.13；R737.14；R737.15；R737.16；R737.17；R737.18；R737.19；R737.20；R737.21；R737.22；R737.23；R737.24；R737.25；R737.26；R737.27；R737.28；R737.29；R737.30；R737.31；R737.32；R737.33；R737.34；R737.35；R737.36；R737.37；R737.38；R737.39；R737.40；R737.41；R737.42；R737.43；R737.44；R737.45；R737.46；R737.47；R737.48；R737.49；R737.50；R737.51；R737.52；R737.53；R737.54；R737.55；R737.56；R737.57；R737.58；R737.59；R737.60；R737.61；R737.62；R737.63；R737.64；R737.65；R737.66；R737.67；R737.68；R737.69；R737.70；R737.71；R737.72；R737.73；R737.74；R737.75；R737.76；R737.77；R737.78；R737.79；R737.80；R737.81；R737.82；R737.83；R737.84；R737.85；R737.86；R737.87；R737.88；R737.89；R737.90；R737.91；R737.92；R737.93；R737.94；R737.95；R737.96；R737.97；R737.98；R737.99；R738.00；R738.01；R738.02；R738.03；R738.04；R738.05；R738.06；R738.07；R738.08；R738.09；R738.10；R738.11；R738.12；R738.13；R738.14；R738.15；R738.16；R738.17；R738.18；R738.19；R738.20；R738.21；R738.22；R738.23；R738.24；R738.25；R738.26；R738.27；R738.28；R738.29；R738.30；R738.31；R738.32；R738.33；R738.34；R738.35；R738.36；R738.37；R738.38；R738.39；R738.40；R738.41；R738.42；R738.43；R738.44；R738.45；R738.46；R738.47；R738.48；R738.49；R738.50；R738.51；R738.52；R738.53；R738.54；R738.55；R738.56；R738.57；R738.58；R738.59；R738.60；R738.61；R738.62；R738.63；R738.64；R738.65；R738.66；R738.67；R738.68；R738.69；R738.70；R738.71；R738.72；R738.73；R738.74；R738.75；R738.76；R738.77；R738.78；R738.79；R738.80；R738.81；R738.82；R738.83；R738.84；R738.85；R738.86；R738.87；R738.88；R738.89；R738.90；R738.91；R738.92；R738.93；R738.94；R738.95；R738.96；R738.97；R738.98；R738.99；R739.00；R739.01；R739.02；R739.03；R739.04；R739.05；R739.06；R739.07；R739.08；R739.09；R739.10；R739.11；R739.12；R739.13；R739.14；R739.15；R739.16；R739.17；R739.18；R739.19；R739.20；R739.21；R739.22；R739.23；R739.24；R739.25；R739.26；R739.27；R739.28；R739.29；R739.30；R739.31；R739.32；R739.33；R739.34；R739.35；R739.36；R739.37；R739.38；R739.39；R739.40；R739.41；R739.42；R739.43；R739.44；R739.45；R739.46；R739.47；R739.48；R739.49；R739.50；R739.51；R739.52；R739.53；R739.54；R739.55；R739.56；R739.57；R739.58；R739.59；R739.60；R739.61；R739.62；R739.63；R739.64；R739.65；R739.66；R739.67；R739.68；R739.69；R739.70；R739.71；R739.72；R739.73；R739.74；R739.75；R739.76；R739.77；R739.78；R739.79；R739.80；R739.81；R739.82；R739.83；R739.84；R739.85；R739.86；R739.87；R739.88；R739.89；R739.90；R739.91；R739.92；R739.93；R739.94；R739.95；R739.96；R739.97；R739.98；R739.99；R740.00；R740.01；R740.02；R740.03；R740.04；R740.05；R740.06；R740.07；R740.08；R740.09；R740.10；R740.11；R740.12；R740.13；R740.14；R740.15；R740.16；R740.17；R740.18；R740.19；R740.20；R740.21；R740.22；R740.23；R740.24；R740.25；R740.26；R740.27；R740.28；R740.29；R740.30；R740.31；R740.32；R740.33；R740.34；R740.35；R740.36；R740.37；R740.38；R740.39；R740.40；R740.41；R740.42；R740.43；R740.44；R740.45；R740.46；R740.47；R740.48；R740.49；R740.50；R740.51；R740.52；R740.53；R740.54；R740.55；R740.56；R740.57；R740.58；R740.59；R740.60；R740.61；R740.62；R740.63；R740.64；R740.65；R740.66；R740.67；R740.68；R740.69；R740.70；R740.71；R740.72；R740.73；R740.74；R740.75；R740.76；R740.77；R740.78；R740.79；R740.80；R740.81；R740.82；R740.83；R740.84；R740.85；R740.86；R740.87；R740.88；R740.89；R740.90；R740.91；R740.92；R740.93；R740.94；R740.95；R740.96；R740.97；R740.98；R740.99；R741.00；R741.01；R741.02；R741.03；R741.04；R741.05；R741.06；R741.07；R741.08；R741.09；R741.10；R741.11；R741.12；R741.13；R741.14；R741.15；R741.16；R741.17；R741.18；R741.19；R741.20；R741.21；R741.22；R741.23；R741.24；R741.25；R741.26；R741.27；R741.28；R741.29；R741.30；R741.31；R741.32；R741.33；R741.34；R741.35；R741.36；R741.37；R741.38；R741.39；R741.40；R741.41；R741.42；R741.43；R741.44；R741.45；R741.46；R741.47；R741.48；R741.49；R741.50；R741.51；R741.52；R741.53；R741.54；R741.55；R741.56；R741.57；R741.58；R741.59；R741.60；R741.61；R741.62；R741.63；R741.64；R741.65；R741.66；R741.67；R741.68；R741.69；R741.70；R741.71；R741.72；R741.73；R741.74；R741.75；R741.76；R741.77；R741.78；R741.79；R741.80；R741.81；R741.82；R741.83；R741.84；R741.85；R741.86；R741.87；R741.88；R741.89；R741.90；R741.91；R741.92；R741.93；R741.94；R741.95；R741.96；R741.97；R741.98；R741.99；R742.00；R742.01；R742.02；R742.03；R742.04；R742.05；R742.06；R742.07；R742.08；R742.09；R742.10；R742.11；R742.12；R742.13；R742.14；R742.15；R742.16；R742.17；R742.18；R742.19；R742.20；R742.21；R742.22；R742.23；R742.24；R742.25；R742.26；R742.27；R742.28；R742.29；R742.30；R742.31；R742.32；R742.33；R742.34；R742.35；R742.36；R742.37；R742.38；R742.39；R742.40；R742.41；R742.42；R742.43；R742.44；R742.45；R742.46；R742.47；R742.48；R742.49；R742.50；R742.51；R742.52；R742.53；R742.54；R742.55；R742.56；R742.57；R742.58；R742.59；R742.60；R742.61；R742.62；R742.63；R742.64；R742.65；R742.66；R742.67；R742.68；R742.69；R742.70；R742.71；R742.72；R742.73；R742.74；R742.75；R742.76；R742.77；R742.78；R742.79；R742.80；R742.81；R742.82；R742.83；R742.84；R742.85；R742.86；R742.87；R742.88；R742.89；R742.90；R742.91；R742.92；R742.93；R742.94；R742.95；R742.96；R742.97；R742.98；R742.99；R743.00；R743.01；R743.02；R743.03；R743.04；R743.05；R743.06；R743.07；R743.08；R743.09；R743.10；R743.11；R743.12；R743.13；R743.14；R743.15；R743.16；R743.17；R743.18；R743.19；R743.20；R743.21；R743.22；R743.23；R743.24；R743.25；R743.26；R743.27；R743.28；R743.29；R743.30；R743.31；R743.32；R743.33；R743.34；R743.35；R743.36；R743.37；R743.38；R743.39；R743.40；R743.41；R743.42；R743.43；R743.44；R743.45；R743.46；R743.47；R743.48；R743.49；R743.50；R743.51；R743.52；R743.53；R743.54；R743.55；R743.56；R743.57；R743.58；R743.59；R743.60；R743.61；R743.62；R743.63；R743.64；R743.65；R743.66；R743.67；R743.68；R743.69；R743.70；R743.71；R743.72；R743.73；R743.74；R743.75；R743.76；R743.77；R743.78；R743.79；R743.80；R743.81；R743.82；R743.83；R743.84；R743.85；R743.86；R743.87；R743.88；R743.89；R743.90；R743.91；R743.92；R743.93；R743.94；R743.95；R743.96；R743.97；R743.98；R743.99；R744.00；R744.01；R744.02；R744.03；R744.04；R744.05；R744.06；R744.07；R744.08；R744.09；R744.10；R744.11；R744.12；R744.13；R744.14；R744.15；R744.16；R744.17；R744.18；R744.19；R744.20；R744.21；R744.22；R744.23；R744.24；R744.25；R744.26；R744.27；R744.28；R744.29；R744.30；R744.31；R744.32；R744.33；R744.34；R744.35；R744.36；R744.37；R744.38；R744.39；R744.40；R744.41；R744.42；R744.43；R744.44；R744.45；R744.46；R744.47；R744.48；R744.49；R744.50；R744.51；R744.52；R744.53；R744.54；R744.55；R744.56；R744.57；R744.58；R744.59；R744.60；R744.61；R744.62；R744.63；R744.64；R744.65；R744.66；R744.67；R744.68；R744.69；R744.70；R744.71；R744.72；R744.73；R744.74；R744.75；R744.76；R744.77；R744.78；R744.79；R744.80；R744.81；R744.82；R744.83；R744.84；R744.85；R744.86；R744.87；R744.88；R744.89；R744.90；R744.91；R744.92；R744.93；R744.94；R744.95；R744.96；R744.97；R744.98；R744.99；R745.00；R745.01；R745.02；R745.03；R745.04；R745.05；R745.06；R745.07；R745.08；R745.09；R745.10；R745.11；R745.12；R745.13；R745.14；R745.15；R745.16；R745.17；R745.18；R745.19；R745.20；R745.21；R745.22；R745.23；R745.24；R745.25；R745.26；R745.27；R745.28；R745.29；R745.30；R745.31；R745.32；R745.33；R745.34；R745.35；R745.36；R745.37；R745.38；R745.39；R745.40；R745.41；R745.42；R745.43；R745.44；R745.45；R745.46；R745.47；R745.48；R745.49；R745.50；R745.51；R745.52；R745.53；R745.54；R745.55；R745.56；R745.57；R745.58；R745.59；R745.60；R745.61；R745.62；R745.63；R745.64；R745.65；R745.66；R745.67；R745.68；R745.69；R745.70；R745.71；R745.72；R745.73；R745.74；R745.75；R745.76；R745.77；R745.78；R745.79；R745.80；R745.81；R745.82；R745.83；R745.84；R745.85；R745.86；R745.87；R745.88；R745.89；R745.90；R745.91；R745.92；R745.93；R745.94；R745.95；R745.96；R745.97；R745.98；R745.99；R746.00；R746.01；R746.02；R746.03；R746.04；R746.05；R746.06；R746.07；R746.08；R746.09；R746.10；R746.11；R746.12；R746.13；R746.14；R746.15；R746.16；R746.17；R746.18；R746.19；R746.20；R746.21；R746.22；R746.23；R746.24；R746.25；R746.26；R746.27；R746.28；R746.29；R746.30；R746.31；R746.32；R746.33；R746.34；R746.35；R746.36；R746.37；R746.38；R746.39；R746.40；R746.41；R746.42；R746.43；R746.44；R746.45；R746.46；R746.47；R746.48；R746.49；R746.50；R746.51；R746.52；R746.53；R746.54；R746.55；R746.56；R746.57；R746.58；R746.59；R746.60；R746.61；R746.62；R746.63；R746.64；R746.65；R746.66；R746.67；R746.68；R746.69；R746.70；R746.71；R746.72；R746.73；R746.74；R746.75；R746.76；R746.77；R746.78；R746.79；R746.80；R746.81；R746.82；R746.83；R746.84；R746.85；R746.86；R746.87；R746.88；R746.89；R746.90；R746.91；R746.92；R746.93；R746.94；R746.95；R746.96；R746.97；R746.98；R746.99；R747.00；R747.01；R747.02；R747.03；R747.04；R747.05；R747.06；R747.07；R747.08；R747.09；R747.10；R747.11；R747.12；R747.13；R747.14；R747.15；R747.16；R747.17；R747.18；R747.19；R747.20；R747.21；R747.22；R747.23；R747.24；R747.25；R747.26；R747.27；R747.28；R747.29；R747.30；R747.31；R747.32；R747.33；R747.34；R747.35；R747.36；R747.37；R747.38；R747.39；R747.40；R747.41；R747.42；R747.43；R747.44；R747.45；R747.46；R747.47；R747.48；R747.49；R747.50；R747.51；R747.52；R747.53；R747.54；R747.55；R747.56；R747.57；R747.58；R747.59；R747.60；R747.61；R747.62；R747.63；R747.64；R747.65；R747.66；R747.67；R747.68；R747.69；R747.70；R747.71；R747.72；R747.73；R747.74；R747.75；R747.76；R747.77；R747.78；R747.79；R747.80；R747.81；R747.82；R747.83；R747.84；R747.85；R747.86；R747.87；R747.88；R747.89；R747.90；R747.91；R747.92；R747.93；R747.94；R747.95；R747.96；R747.97；R747.98；R747.99；R748.00；R748.01；R748.02；R748.03；R748.04；R748.05；R748.06；R748.07；R748.08；R748.09；R748.10；R748.11；R748.12；R748.13；R748.14；R748.15；R748.16；R748.17；R748.18；R748.19；R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FOSUNKite 有效性: 阿基仑赛注射液给复发/难治LBCL患者带来治愈机会

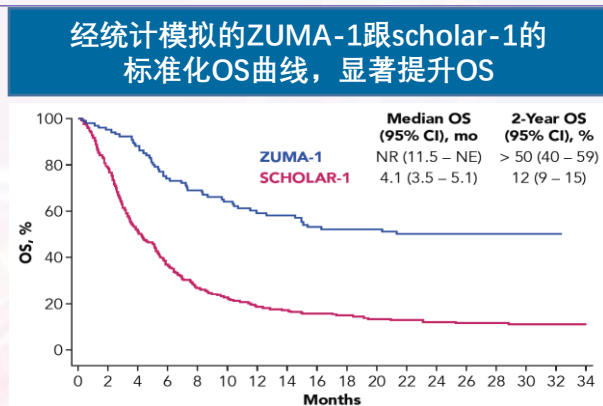
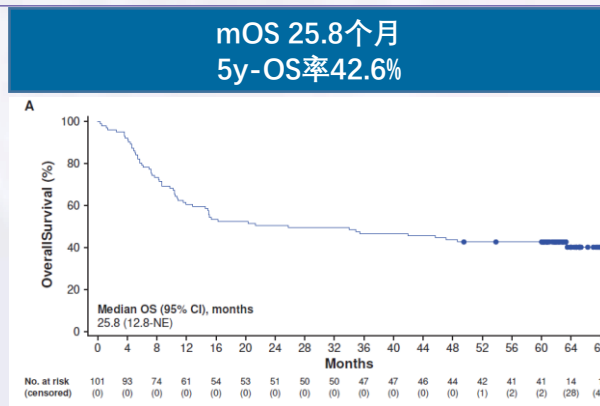
— 复星凯特生物 —

ZUMA-1
阿基仑赛用于
3线及以上LBCL
(101例) 1, 2

主要研究终点bORR: 83%

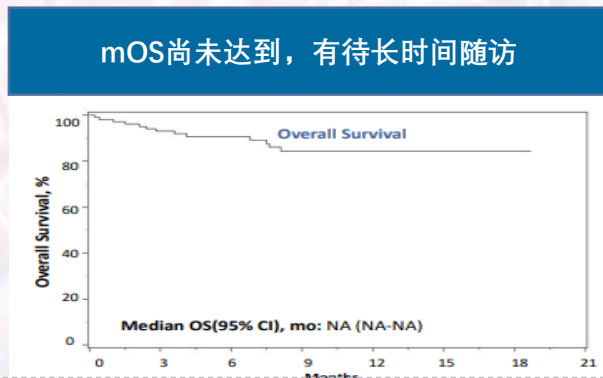
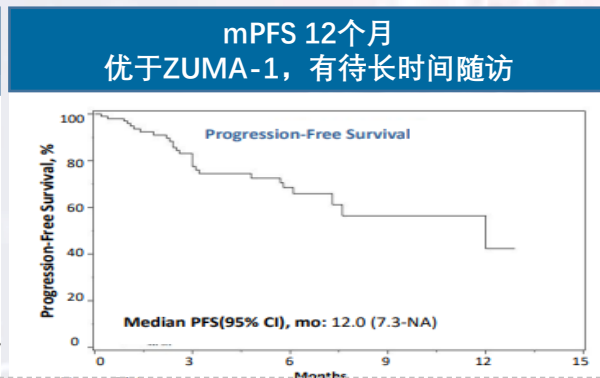
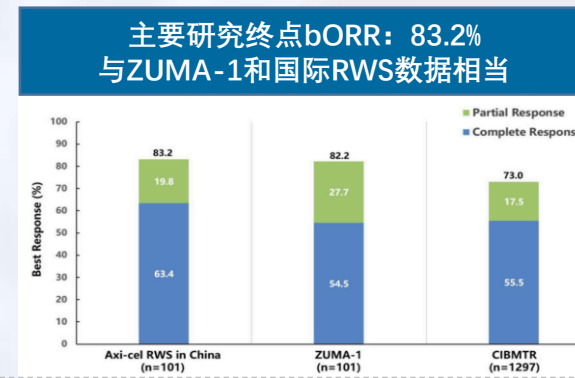
N=101

Best Response, n (% , 95% CI)	
Objective response	84 (83, 74-90)
CR	59 (58, 48-68)
PR	25 (25, 17-34)



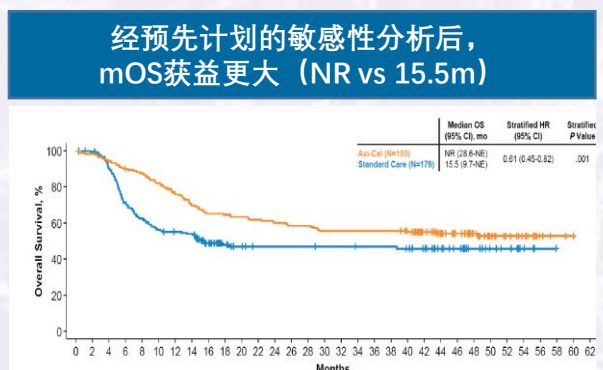
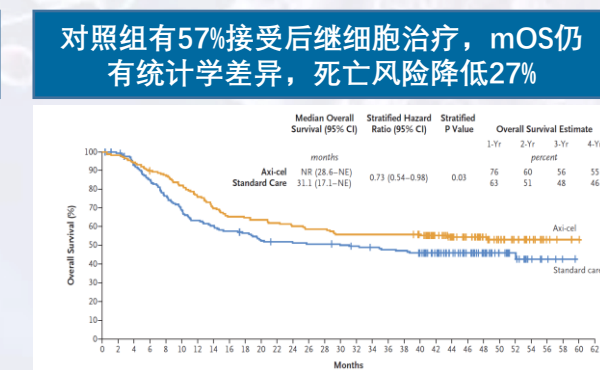
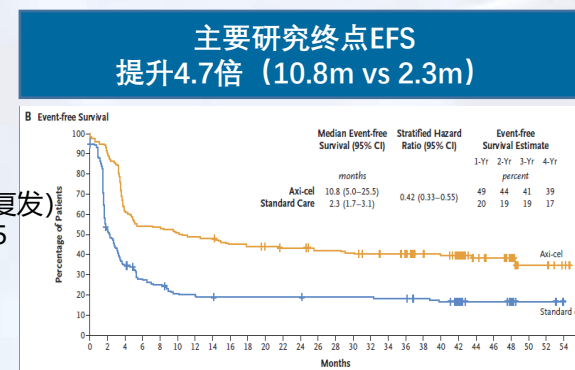
① 提高缓解率

中国RWS
阿基仑赛用于
中国R/R NHL
(101例) 3, 4



② 延长患者生存期

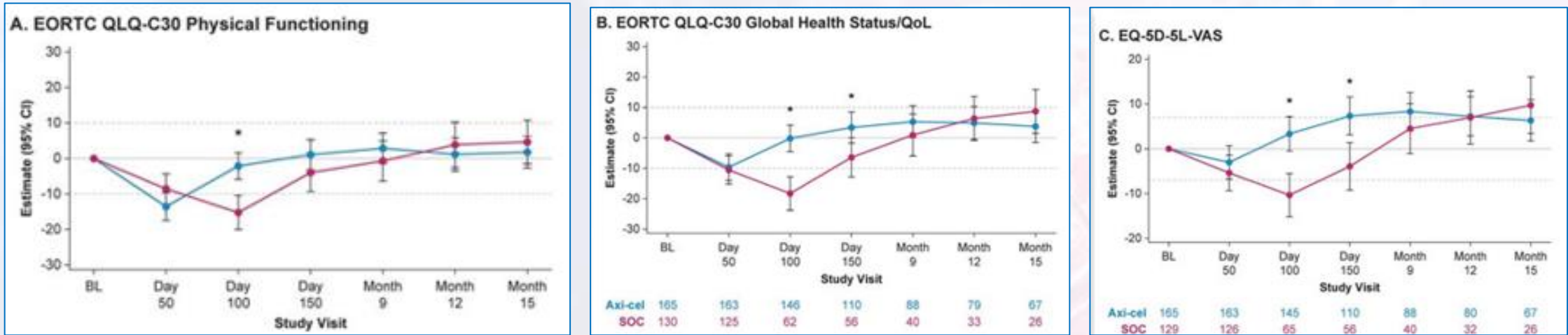
ZUMA-7
阿基仑赛 vs SOC
用于2L LBCL
(原发难治&一线治疗后12个月内复发)
(180例 vs 179例) 5



③ 降低患者死亡风险

1. Lancet Oncol. 2019 Jan;20(1):31-42. 2. Blood Adv. 2021 Oct 26;5(20):4149-4155. 3. Wang L, et al. 2023 EHA- Poster 1203. 4. 2023 ICML-Poster 337. 5. N Engl J Med. 2023 Jul 13;389(2):148-157.

④ 对患者生活质量方面显示出有临床意义的改善¹



	第100天	第150天	9个月后
EORTC QLQ-C30 功能和症状	P<0.0001	无差异	无差异
EORTC QLQ-C30 健康状况/ 生活质量	P<0.0001	P=.0124	无差异
EQ-5D-5L	P<0.0001	=.0004	无差异
结论	<ul style="list-style-type: none"> • 在第100天时，在所有PRO评估系统中，阿基仑赛注射液均比对照组更有利于改善患者的生活质量。 • 9个月后，两组PRO评分无差异是由于对照组死亡人数多，数据脱落多，比较误差大，临床意义不充分。 		

中国CSCO2023指南推荐



- **既往2线及以上**DLBCL患者无论是否符合移植条件，均推荐CAR-T细胞治疗（I级推荐）
- **原发难治或12个月内复发**的初次复发/进展符合移植条件DLBCL患者推荐CAR-T细胞治疗（I级推荐）
- **初次复发/进展不符合移植条件**DLBCL患者推荐CAR-T治疗（II级推荐）

美国NCCN2024指南推荐



- 对于“**原发难治或 < 12个月复发**”的二线DLBCL患者，**1类推荐CD19 CAR-T**
- 对于“**> 12个月复发/难治且有移植意向**”的二线DLBCL患者，如挽救治疗为**PR**，推荐CD19 CAR-T治疗
- 对于“**> 12个月复发/难治且无移植意向**”的二线DLBCL患者，推荐CD19 CAR-T
- 对于**既往2线及以上**系统性治疗的R/R DLBCL患者，推荐CD19 CAR-T治疗

中华医学会淋巴瘤指南



- **既往2线及以上系统性治疗未达CR**的DLBCL患者

卫健委指南推荐



中华人民共和国国家卫生健康委员会
National Health Commission of the People's Republic of China

- **既往2线及以上系统性治疗失败**DLBCL患者，可选择CD19 CAR-T细胞治疗

CDE技术审批报告

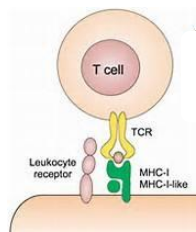
- 阿基仑赛注射液是基于关键临床研究ZUMA-7、FK876治疗二线或以上系统性治疗后R/R LBCL中国桥接临床试验（FKC876-2018-001）的2年疗效、本品上市后中国真实世界临床研究（FKC876-2020-001）的疗效及其他真实世界研究结果获批增加LBCL二线适应症。
- ZUMA-7研究证实**阿基仑赛注射液与二线标准治疗相比治疗一线免疫化疗后复发性或难治性LBCL受试者具有显著疗效优势**。二线治疗以上国内外患者人群中的长期（2年）生存率较接近。国内外患者人群中真实世界的有效性结果基本一致。国内外人群中的安全性特征总体一致，国内人群中 ≥ 3 级神经毒性发生率更低。

- 阿基仑赛注射液是全球首个获批治疗LBCL的CAR-T产品，也是中国首个获批上市的CAR-T产品，实现了CAR-T治疗产品国内的零突破，开启了我中国细胞疗法元年；目前也是唯一获批用于2L LBCL治疗的CAR-T产品。

机制创新

- 阿基仑赛是通过基因工程在自体T细胞中表达嵌合抗原受体（CAR）来靶向肿瘤抗原CD19，通过T细胞介导来杀伤肿瘤细胞的药物。其结构包括：单链可变区片段（scFv）、共刺激分子CD28跨膜区及CD3-ζ胞内信号结构域。
- CD19是仅在B细胞中表达的跨膜蛋白。多数LBCL患者反复发后对常规化疗抵抗，部分LBCL患者初始治疗即对免疫化疗耐药。阿基仑赛不同的作用机制导致了其对复发难治LBCL的疗效显著提升。

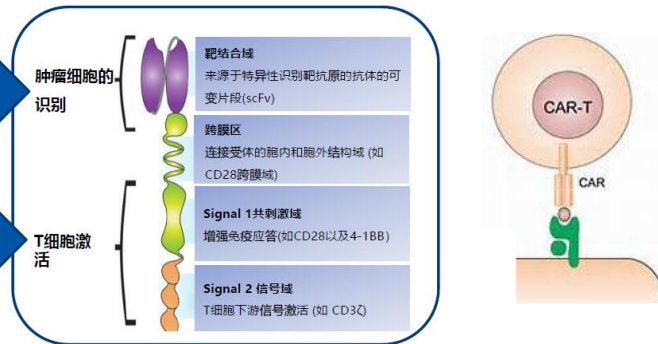
各代CAR-T的机构具有共同性，主要由肿瘤识别结构域和T细胞活化结构域组成^{1,2}



1 通过改造T细胞表面的识别结构域（通常scFv）靶向肿瘤细胞

2 通过CAR胞内信号域的信号传导激活CAR-T细胞

- T细胞的激活与扩增
- CAR-T细胞介导的肿瘤细胞杀伤



优先审评

2020年3月，国家药品监督管理局药品审评中心将阿基仑赛上市申请纳入**优先审评**

突破性治疗药物

2021年8月17日被纳入中国药品监督管理局**突破性治疗药物**

二线适应症免临床试验

2022年10月14日，国家药品监督管理局药品审评中心正式受理阿基仑赛注射液二线适应症并纳入**优先审评**品种名单；2023年6月21日，二线适应症正式获批上市

特殊人群

对于**老年患者**疗效更佳。阿基仑赛3线和2线注册研究（ZUMA-1和ZUMA-7），以及中国RWS研究均显示≥65岁人群亚组疗效优于研究整体人群。

应用创新

阿基仑赛注射液为一次性输注产品，仅需**一次静脉输注，无需重复给药**

对公共健康的影响

延长患者生命，助力公共健康目标

- LBCL是我国常见的血液系统恶性肿瘤，危害性大、死亡率高；
- 阿基仑赛注射液给患者带来了持久的缓解，帮助延长患者的生存期，三线复发难治性LBCL患者**5年OS率为42.6%¹**；
- 原发难治和一线治疗后12个月内复发的LBCL患者经阿基仑赛治疗，**4年OS率为54.6%**，有治愈可能，且生活质量更高。

弥补目录短板

中国首个治疗LBCL的CAR-T产品

- 全球及**中国首个**获批上市的、治疗LBCL的CAR-T产品；
- 我国复发难治的LBCL患者中位OS仅为5.9月，现有治疗手段难以有效延长患者生存，治愈可能性极低。因此对于疗效确切，安全性良好的创新药物需求迫在眉睫。
- 阿基仑赛注射液能够满足有效**延长患者生存期（本品5年OS 42.6%）¹**，提高生命质量、实现潜在临床治愈的需求，弥补了临床空白及目录短板。

可预见的治愈

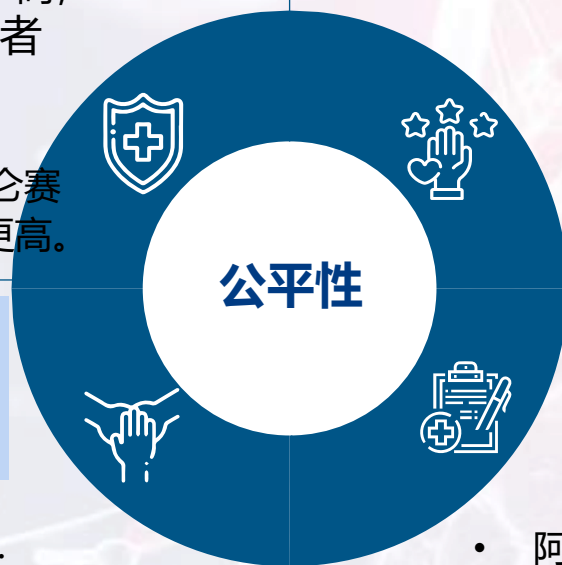
满足患者长期生存获益，减轻患者负担

- 5年生存的患者中**92%不需要额外的抗癌治疗¹**，实现潜在的临床治愈，帮助患者回归正常生活，社会获益显著。

便于临床管理

高质量控制体系，临床滥用风险低

- 阿基仑赛注射液为**一次性输注产品**，不易被滥用，便于临床管理；
- 阿基仑赛注射液为**个性化定制药物**，对患者所需药品的专有性设置了系统性风险防控体系；
- 说明书²明确要求“在经过上市许可持有人评估和培训的医疗机构内使用本品、应在具有血液学恶性肿瘤治疗经验并接受过本产品给药及患者治疗管理培训的医务人员的指导和监督下进行”，确保**规范化的用药**。



公平性