



**BRIGHTGENE BIO-MEDICAL
TECHNOLOGY CO., LTD.**

博瑞生物医药（苏州）股份有限公司

Innovation Never Stops



www.bright-gene.com

About BrightGene

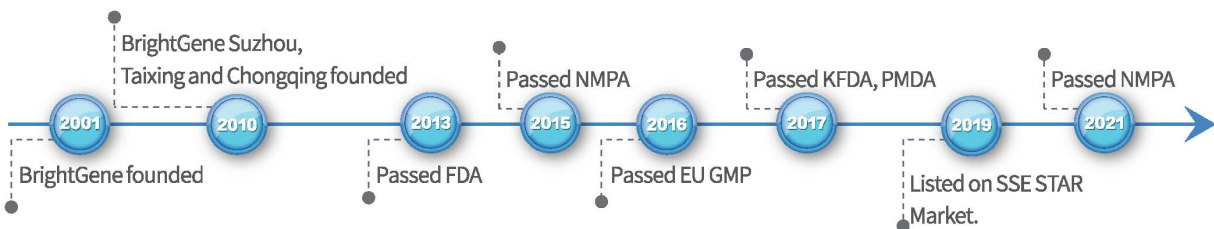
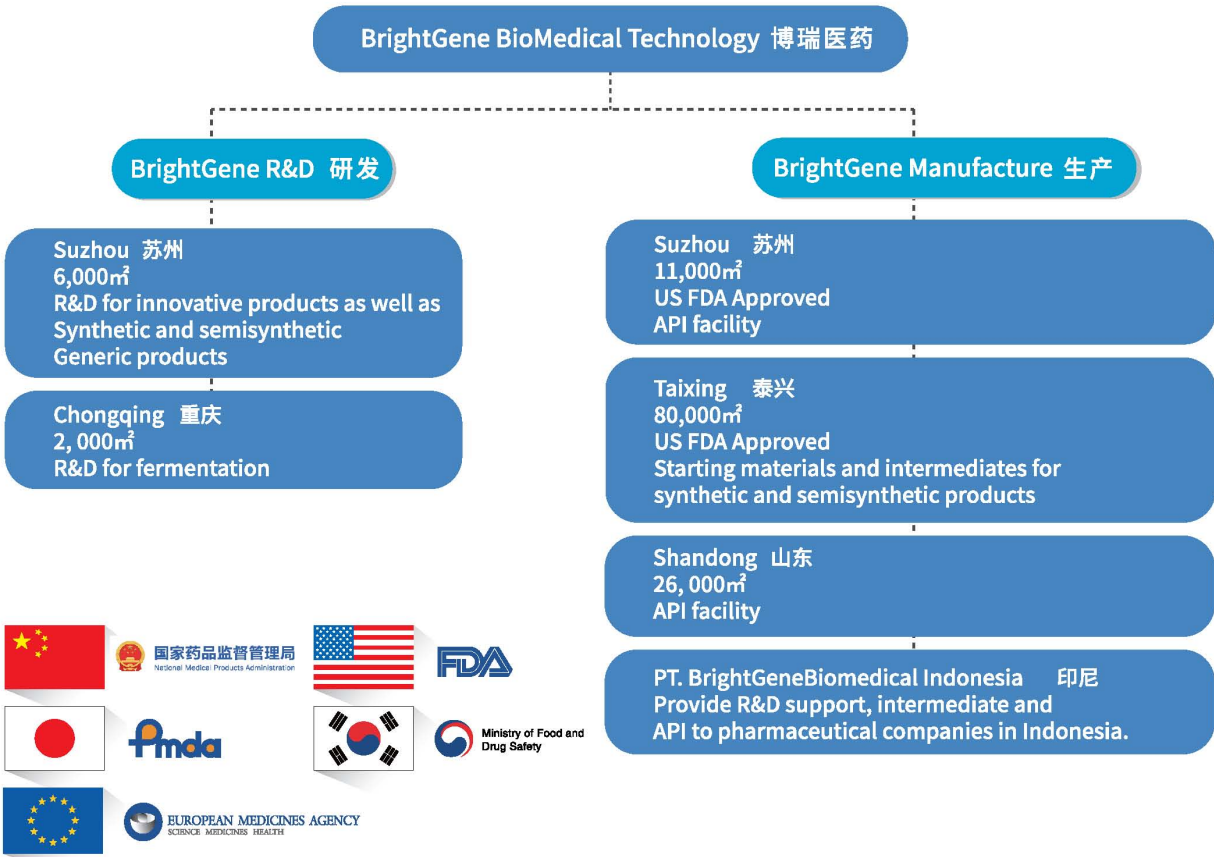
(A Sustainable innovative Company)

BrightGene Bio-Medical Technology Co., Ltd, is a research driven pharmaceutical company that engages in the R&D and manufacturing of innovative medicine as well as special generic APIs and FDFs. We provide high-quality products and technical services to global customers with strong development capabilities, world-class production systems and commercialization capabilities. BrightGene has cGMP compliance factories, and has got approval from USFDA, EU, PMDA, KFDA and CFDA.

博瑞生物医药(苏州)股份有限公司(股票简称:博瑞医药;股票代码:688166)

位于苏州工业园区风景秀丽的独墅湖畔,由海归博士袁建栋先生于2001年创立,专注于研发和生产创新药和市场稀缺的高难度仿制药,以极强的产品开发能力、国际一流的生产体系和商业化能力为全球客户提供高质量的产品和技术服务。

Group Branches



在研产品/Pipeline Products

Usage	Name	CAS No.	Status	Marketing Exclusivity & Patent
Anti-infection/ 抗感染	Amphotericin B 两性霉素B	1397-89-3	validated	N/A Off-patent
	Josamycin 交沙霉素	16846-24-5	Pilot	N/A Off-patent
	Josamycin propionate 丙酸交沙霉素	40922-77-8	Pilot	N/A Off-patent
	Nystatin 制霉菌素	1400-61-9	Pre-validation	N/A Off-patent
	Omadacycline 奥马环素	1075240-43-5	Pre-validation	NCE : 2023-10-02 GAIN : 2028-10-02 Off-patent
	Oritavancin 奥利万星	171099-57-3	Pre-validation	NCE : 2019-08-06 NP : 2024-03-12 GAIN : 2024-08-06 Off-patent
Oncology/ 抗肿瘤	Apalutamide 阿帕鲁胺	956104-40-8	R&D	I-808 : 2022-09-17 NCE : 2023-02-14 CN : 2027-03-27 US : 2030-09-15 EP : 2026-03-29
	★ Lurbinectedin 卢比替丁	497871-47-3	Pilot	NCE : 2025-06-15 ODE : 2027-06-15 US : 2024-12-13 EP : Off-patent
	Relugolix 瑞卢戈利	737789-87-6	R&D	NP : 2024-05-26 NCE : 2025-12-18 US : 2024-01-28 CN : 2024-01-28 EP : 2024-01-28
Gynecology/ 妇科	Dydrogesterone 地屈孕酮	152-62-5	Pilot	N/A Off-patent
Cardiovascular/ 心脑血管	★ Ethyl Icosapentate 鱼油	86227-47-6	Pre-validation	NP : 2015-07-26 NCE : 2017-07-26 I-819 : 2022-12-13 Off-patent
Contrast medium/ 造影剂	Gadobutrol 钆布醇	138071-82-6	Pilot	NCE : 2016-03-14 I-688 : 2017-06-11 I-731 : 2019-04-27 I-801 : 2022-07-12 Off-patent
	Iodixanol 碘克沙醇	92339-11-2	Pilot	I-752 : 2020-04-05 Off-patent
	Iomeprol 碘美普尔	78649-41-9	Pilot	N/A Off-patent
Parkinson/ 帕金森	Cabergoline 卡麦角林	81409-90-7	Pilot	N/A Off-patent
Immunosuppressant 免疫抑制	Mycophenolate Sodium 麦考酚钠	37415-62-6	Pre-validation	N/A Off-patent
	★ Tacrolimus 他克莫司	104987-11-3	Pre-validation	ODE : 2013-03-29 ODE-294 : 2025-05-24 ODE-360 : 2028-07-16 Off-patent
	★ Voclosporin 伏环孢素	515814-01-4	R&D	NCE : 2026-01-22 Off-patent
Antifungal/ 抗真菌	★ Ibrexafungerp 艾瑞芬净	1207753-03-4	R&D	NCE : 2026-06-01 GAIN : 2031-06-01 CN : 2029-08-07 US : 2030-08-28 EP : Off-patent

商业化/Commercialized

Usage	Name	CAS No.	Status	Marketing Exclusivity & Patent
Antifungal/ 抗真菌	Anidulafungin 阿尼芬净	166663-25-8	DMF No.: 032010 ASMF Approved	NCE:2011-02-17 NPP:2023-09-22 Off-patent
	Caspofungin Acetate 醋酸卡泊芬净	179463-17-3	DMF No.: 034091 ASMF Approved	I-438:2007-09-29 Off-patent
	* Isavuconazonium sulfate 艾沙康唑	241479-67-4	DMF to be ready	NCE:2020-03-06 ODE:2022-03-06 GAIN:2025-03-06 GAIN:2027-03-06 EP:Off-patent US:2025-10-31
	Micafungin Sodium 米卡芬净钠	208538-73-2	DMF No.: 031449 ASMF Approved MF No.: 230MF10169	NCE:2011-03-16 PED:2023-06-20 I-821:2022-12-20 I-554:2011-01-22 Off-patent
	Posaconazole (amorphous) 泊沙康唑(无定型)	171228-49-2	DMF No.: 028314	NCE:2011-09-15 Off-patent
	Posaconazole(Form I) 泊沙康唑(晶型 I)	171228-49-2	DMF No.: 032346	NCE:2011-09-15 Off-patent
Anti-infection/ 抗感染	Posaconazole(Form III) 泊沙康唑(晶型III)	171228-49-2	DMF No.: 030886	NCE:2011-09-15 Off-patent
	Dalbavancin Hydrochloride 盐酸达巴万星	N/A	DMF No.: 035874	NCE:2019-05-23 NPP:2024-07-22 GAIN:2024-05-23 D-154:2019-01-20
	Fidaxomicin 非达霉素	873857-62-6	DMF No.: 028803	NCE:2016-05-27 NPP:2023-01-24 PED:2023-07-24 ODE-367:2027-01-24 US:2024-01-23 EP:Off-patent CN:2025-01-31
	Ianinamivir octanoate 辛酸拉尼米韦	203120-46-1	DMF Ready	N/A Off-patent
Anticoagulant/ 抗凝	Tebipenam Pivoxil 替比培南酯	161715-24-8	DMF Ready	N/A Off-patent
	Argatroban 阿加曲班	141396-28-3	DMF No.: 035491 MF No.: 230MF10028 302MF10033	M-75:2011-05-05 Off-patent
	Fondaparinux Sodium 磺达肝癸钠	114870-03-0	DMF No. : 030767	NCE:2006-12-07 NS:2007-05-31 I-426:2007-05-31 I-426:2007-05-31 I-457:2008-05-26 Off-patent
Oncology/ 抗肿瘤	Eribulin Mesilate 甲磺酸艾瑞布林	441015-17-6	DMF No. : 035118	NCE:2015-11-15 I-721:2019-01-28 ODE:2023-01-28 US:2023.07.20 CN:Off-patent EP:Off-patent
	Everolimus (0.2% BHT) 依维莫司(0.2%BHT)	159351-69-6	DMF Ready	NCE:2014-03-30 ODE:2023-02-26 Off-patent
	Everolimus(2.0% BHT) 依维莫司(2.0% BHT)	159351-69-6	DMF No.: 032020	NCE:2014-03-30 ODE:2023-02-26 Off-patent

Usage	Name	CAS No.	Status	Marketing Exclusivity & Patent
Oncology/ 抗肿瘤	Everolimus (without BHT) 依维莫司(不含BHT)	159351-69-6	MF No.:230MF10023	NCE:2014-03-30 ODE:2023-02-26 Off-patent
	Midostaurin 米哌妥林	120685-11-2	DMF Ready	NCE:2022-04-28 ODE:2024-04-28 Off-patent
	Trabectedin 曲贝替定	114899-77-3	ASMF Filed	NCE:2020-10-23 ODE:2022-10-23 PED:2023-04-23 M-232:2021-06-29 US:2028-07-07 EP:2025-10-12 CN:2025-10-28
Anti-viral/ 抗病毒	Entecavir Monohydrate 恩替卡韦	209216-23-9	DMF No.:031949 CEP No.:2018-283	NCE:2010-03-29 NPP:2017-03-20 PED:2017-09-20 D-127:2013-10-15 Off-patent
	Oseltamivir Phosphate 磷酸奥司他韦	204255-11-8	DMF No.:035876	PED:2009-06-21 NPP:2015-12-21 I-480:2008-12-21 M-215:2022-08-02 Off-patent
PBC&NASH/ 肝病	Obeticholic Acid 奥贝胆酸	459789-99-2	DMF No.:036292	NCE:2021-05-27 ODE:2023-05-27 US:2022-11-16 CN: Off-patent EP: Off-patent
Selective relaxant binding agent/ 选择性肌松剂	Sugammadex Sodium 舒更葡糖钠	343306-79-6	DMF No.:033904 ASMF filed	NCE:2020-12-15 NPP:2024-06-25 M-262:2023-06-09 US:2026-01-27 CN: Off-patent EP: Off-patent
Immunosuppressant /免疫抑制	Pimecrolimus 吡美莫司	137071-32-0	DMF No.:030090	NCE:2006-12-13 PED:2007-06-13 Off-patent
Pesticide(human use) /驱虫剂	Spinosad 多杀菌素	131929-60-7	DMF No.:036293	NCE:2016-01-18 M-152:2017-11-30 I-858:2024-04-28 Off-patent
Osteoporosis/ 骨质疏松	Eldecalcitol 艾地骨化醇	104121-92-8	DMF Ready	N/A Off-patent
Contrast medium/ 造影剂	Iopromide 碘普罗胺	73334-07-3	DMF Ready	N/A Off-patent
	Regadenoson 瑞加诺生	313348-27-5	DMF Ready	NCE:2013-04-10 M-194:2020-01-17 Off-patent
Cardiovascular/ 心脑血管	Nicergoline 尼麦角林	27848-84-6	DMF Ready	N/A Off-patent
Gynecology/ 妇科	Carboprost tromethamine 卡前列素氨基丁三醇	58551-69-2	DMF No.:037422	CGT:2019-12-29 Off-patent
	Dienogest 地诺孕素	65928-58-7	DMF Ready	I-648:2015-03-14 Off-patent

补铁剂/Iron Supplement

Name	CAS No.	Status	Marketing Exclusivity & Patent
Ferric carboxymaltose/ 羧基麦芽糖铁	9007-72-1	Validated	NP:2016-07-25 NS:2024-04-28 NPP:2024-11-19 US:2024.02.05 CN:2023.10.20 EP:2023.10.20
Ferric citrate hydrate 柠檬酸铁四水合物	2338-05-8	Pilot	N/A Off-patent
Ferric Pyrophosphate Citrate 焦磷酸铁钠	1332-96-3	Pilot	N/A US:2029-04-17 EP:2028-07-08 CN:Off-patent
Ferumoxytol 超顺磁纳米氧化铁	722492-56-0	Pilot	N/A Off-patent
Iron Sucrose/ 蔗糖铁	8047-67-4	Pre-validation	N/A Off-patent

兽药/Veterinary

Name	CAS No.	Status	Patent
Doramectin 多拉菌素	117704-25-3	Validated	Off-patent
Emodepside 艾默德斯	155030-63-0	Validated	CN:2025-11-03(用途) US:Off-patent EP:2025-11-03
Fluralaner 氟雷拉纳	864731-61-3	Pre-validation	CN:2025-03(化合物) CN:2034-12(用途) US:2025-04-26 EP:2025-03-04
Milbemycin Oxime 米尔贝肟	129496-10-2	Pilot	Off-patent
Moxidectin 莫昔克丁	113507-06-5	Pilot	Off-patent
Pradofloxacin 普多沙星	195532-12-8	Pilot	Off-patent
Selamectin 赛拉菌素	165108-07-6	Pre-validation	Off-patent
Spinosad 多杀霉素	131929-60-7	DMF ready	Off-patent

中间体/Intermediate

用途/Usage	Name	CAS No.	Status
For Fondaparinux Sodium	FSC 磺达肝癸钠中间体	114903-05-8	DMF No.: 028552
For Entecavir	ET1 恩替卡韦中间体	142217-81-0	DMF No.: 026257
For Micafungin	MFA 米卡芬净钠中间体	168110-44-9	DMF No.: 030028
For Micafungin	MFB 米卡芬净钠中间体	179162-55-1	DMF No.: 033892
For Posaconazole	POA 泊沙康唑中间体 (POA)	149809-43-8	DMF No.: 033193
For Posaconazole	POB 泊沙康唑中间体 (POB)	184177-83-1	DMF No.: 033194
For Anidulafungin	Echinocandin B0 棘白菌素B0	79411-15-7	DMF Ready
For Caspofungin	Pneumocandin B0 纽莫康定 B0	135575-42-7	DMF No.: 034006
For Agatrobam	AGC 阿加曲班中间体	74874-08-1	Validated
For Trabectedin	Safracin B 曲贝替定中间体	87578-99-2	Pre-validation
For Trabectedin	Cyanosafracin B 曲贝替定中间体	96996-50-8	Pre-validation
For Oritavancin	CBR49 奥利万星母核	118395-73-6	Pre-validation
For Alvimopan	AMA 阿维莫潘中间体	119193-19-0	Validated
For Alvimopan	AMB 阿维莫潘中间体	1314751-85-3	Validated
Oncology	Pemetrexed disodium intermediate 培美曲塞二钠中间体	137281-39-1	DMF No.: 031215
Oncology	Ascomycin 子囊霉素	104987-12-4	DMF No.: 029433
Oncology	Staurosporine 星孢菌素	62996-74-1	DMF No.: 034763
For Saxagliptin	SGA 沙格列汀中间体	361442-00-4	Commercial
For Saxagliptin	SGB 沙格列汀中间体	361440-67-7	Commercial
For Everolimus	Sirolimus 西罗莫司	53123-88-9	DMF No.: 035527
For Dalbavancin Hydrochloride	CBR48 盐酸达巴万星母核	110882-84-3	DMF ready

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