Product Portfolio

Development and Licensing Opportunities

bluepharma

Available Dossiers | New

Product	Dosage Form | Strength	Reference Product EU* | US	Indication	Product Protection Expiration	
				EU*	US
Abiraterone	tabs. | 250mg	Zytiga®	Oncology	09/2022 (ME)	-
Abiraterone	f.c. tabs. | 500mg	Zytiga®	Oncology	09/2022 (ME)	-
Alprazolam	tabs. | 0.25mg, 0.5mg, 1mg	Xanax®	Anxiety	-	-
Amlodipine	tabs. | 5mg, 10mg	Norvasc®	Hypertension	-	-
Azithromycin	f.c. tabs. | 250mg, 500mg, 600mg	Zithromax®	Anti-infective	-	-
Ephedrine	injection | 50mg/mL	n.a. | Akovaz®	Hypotension occurring in the setting of anesthesia	-	-
Febuxostat	f.c. tabs. | 80mg, 120mg	Adenuric® | Uloric®	Chronic gout	-	-
Fingolimod	caps. | 0.25mg [2], 0.5mg	Gilenya®	Multiple Sclerosis	TBD	12/2027 (PAT)
Gefitinib	f.c. tabs. | 250mg	Iressa®	Oncology	-	-
Palbociclib	caps. | 75mg, 100mg, 125mg	Ibrance®	Oncology	01/2028 (SPC)	03/2027 (PAT)
Paroxetine	f.c. tabs. | 20mg	Seroxat® | Paxil®	Major Depression and Anxiety Disorders	-	-
Rivaroxaban	f.c. tabs. | 2.5mg, 10mg, 15mg, 20mg	Xarelto®	Anti-thrombotic	01/2026 (PAT)	08/2034 (PED)
Sitagliptin	tabs. | 25mg, 50mg, 100mg	Januvia®	Diabetes Mellitus	09/2022 (PED)	07/2023 (PED + 180d)
Sitagliptin + Metformin	tabs. | 50 + 500mg, 50 + 850mg, 50 + 1000mg	Janumet®	Diabetes Mellitus	09/2022 (PED)	07/2023 (PED + 180d)
Sunitinib	caps. | 12.5mg, 25mg, 37.5mg, 50mg	Sutent®	Oncology	-	-
Tofacitinib [1]	f.c. tabs. | 5mg, 10mg [2]	Xeljanz®	Rheumatoid, Psoriatic Arthritis, and Ulcerative Colitis	03/2028 (ME)	12/2025 (PAT)
Valganciclovir	f.c. tabs. | 450mg	Valcyte®	Anti-infective (CMV)	-	-
Vildagliptin	tabs. | 50mg	Galvus® | n.a.	Diabetes Mellitus	09/2022 (SPC)	-
Vildagliptin + Metformin	f.c. tabs. | 50 + 500mg, 50 + 850mg, 50 + 1000mg	Eucreas® | n.a.	Diabetes Mellitus	11/2022 (SPC)	-

* - Germany used as reference [1] - Climatic Zone IVb stability study to be performed under request [2] - Upon request
ME - Market exclusivity with or without new therapeutic indication | NS - New strength exclusivity with clinical investigation | ODE - Orphan Drug Exclusivity | PAT - Patent
PED - Pediatric Exclusivity | PTE - Patent Term Extension | SPC - Supplementary Protection Certificate | TBD - To Be Defined | 180d - Patent challenge 180 day exclusivity

Available Dossiers

Product	Dosage Form | Strength	Reference Product EU* | US	Indication	Product Protection Expiration	
				EU*	US
Acarbose	tabs. | 50mg, 100mg	Glucobay®	Diabetes Mellitus	-	-
Candesartan	tabs. | 4mg, 8mg, 16mg, 32mg	Blopress® | Atacand®	Hypertension	-	-
Candesartan HCTZ	tabs. | 8 + 12.5mg, 16 + 12.5mg	Blopress Plus® | Atacand HCT®	Hypertension	-	-
Ciprofloxacin	f.c. tabs. | 250mg, 500mg, 750mg	Ciproxin® | Cipro®	Anti-infective	-	-
Clarithromycin	f.c. tabs. | 250mg, 500mg	Klaricid® | Biaxin®	Anti-infective	-	-
Clonidine ER	e.r. tabs. | 0.1mg	n.a. | Kapvay®	Attention Deficit Hyperactivity Disorder	-	-
Clopidogrel	tabs. | 75mg	Plavix®	Anti-thrombotic	-	-
Droxidopa	caps. | 100mg, 200mg, 300mg	n.a. | Northera®	Neurogenic Orthostatic Hypotension	-	-
Ezetimibe + Simvastatin	tabs. | 10 + 20mg, 10 + 40mg, 10 + 80mg	Vytorin® | Inegy®	Hypercholesteremia	-	-
Irbesartan	f.c. tabs. | 75mg, 150mg, 300mg	Approvel® | Avapro®	Hypertension	-	-
Irbesartan HCTZ [1]	f.c. tabs. | 150 + 12.5mg, 300 + 12.5mg, 300 + 25mg	Coapprovel® | Avalide®	Hypertension	-	-
Levetiracetam	f.c. tabs. | 250mg, 500mg, 750mg, 1000mg	Keppra®	Epilepsy	-	-
Levetiracetam [1]	oral solution | 100mg/mL	Keppra®	Epilepsy	-	-
Losartan	f.c. tabs. | 12.5mg, 25mg, 50mg, 100mg	Cozaar®	Hypertension	-	-
Losartan HCTZ	f.c. tabs. | 50 + 12.5mg, 100 + 25mg	Cozaar®	Hypertension	-	-
Moxifloxacin	f.c. tabs. | 400mg	Avelox®	Anti-infective	-	-
Nimesulide	tabs. | 100mg	Aulin® | Nimed®	Pain, Inflammation	-	-

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Ongoing developments

Product	Dosage Form | Strength	Reference Product EU* | US	Indication	Product Protection Expiration		Dossier Ready
				EU*	US	
Pazopanib	f.c. tabs. | 200mg, 400mg	Votrient®	Oncology	12/2025 (PED)	10/2023 (PAT)	Upon Request
Pomalidomide	caps. | 1mg, 2mg, 3mg, 4mg	Imnovid® | Pomalyst®	Oncology	08/2024 (ME)	12/2025 (PED + 180d)	Upon Request
Eltrombopag	f.c. tabs. | 12.5mg, 25mg, 50mg, 75mg	Revolade® | Promacta®	Thrombocytopenia	09/2025 (PED)	07/2026 (PED + 180d)	Upon Request
Afatinib	f.c. tabs. | 20mg, 30mg, 40mg, 50mg	Giotrif® | Gilotrif®	Oncology	12/2026 (SPC)	07/2026 (PED + 180d)	Upon Request
Tofacitinib XR	e.r. tabs | 11mg, 22mg	Xeljanz® | Xeljanz XR®	Rheumatoid, Psoriatic Arthritis, and Ulcerative Colitis	03/2028 (ME)	12/2025 (PAT)	Upon Request
Lenvatinib	caps. | 4mg, 10mg	Kisplyx® | Lenvima®	Oncology	10/2026 (SPC)	09/2026 (PAT)	Upon Request
Atorvastatin + Ezetimibe	tabs. | 10 + 10mg, 20 + 10mg, 40 + 10mg, 80 + 10mg	Atozet®/Liptruzet® | n.a.	Hypercholesteremia	09/2024 (ME)	-	Upon Request
Cabozantinib	f.c. tabs. | 20mg, 40mg, 60mg	Cabometyx®	Oncology	01/2030 (PAT)	10/2030 (PAT)	Upon Request
Ibrutinib	f.c. tabs. | 140mg, 280mg, 420mg, 560mg	Imbruvica®	Oncology	10/2029 (SPC)	06/2031 (PAT)	Upon Request
Nilotinib	caps. | 50mg, 150mg, 200mg	Tasigna®	Oncology	07/2023 (PAT)	01/2024 (PED)	Upon Request
Palbociclib	tabs. | 75mg, 100mg, 125mg	Ibrance®	Oncology	01/2028 (SPC)	03/2027 (PAT)	Upon Request
Ruxolitinib	tabs. | 5mg, 10mg, 15mg, 20mg, 25mg	Jakavi® | Jakafi®	Oncology	06/2028 (PAT)	06/2028 (PAT)	Upon Request
Olaparib	f.c. tabs. | 100mg, 150mg	Lynparza®	Oncology	03/2029 (PED)	08/2031 (PAT)	Upon Request

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Complex Generics

Product	Dosage Form Strength	Reference Product EU* | US	Indication	Product Protection Expiration		Status
				EU*	US	
Amphotericin B	liposome injection 50mg/vial	Ambisome®	Fungal infections	-	-	Upon Request
Bupivacaine	liposome injection 13.3mg/mL	Exparel®	Postsurgical analgesia	11/2030 (ME)	TBD	Upon Request
Buprenorphine + Naloxone	sublingual film 2 + 0,5mg, 4 + 1mg, 8 + 2mg, 12 + 3mg	n.a. | Suboxone®	Opioid dependence	-	-	Upon Request
Daunorubicin + Cytarabine	liposome injection 44mg + 100mg/vial	Vyxeos®	Oncology	04/2030 (SPC)	04/2029 (PAT)	Upon Request
Dihydroergotamine	nasal spray 4mg/mL	n.a. | Migranal®	Migraine	-	-	Available
Doxorubicin	liposome injection 2mg/mL	Caelyx® | Doxil®	Oncology	-	-	Upon Request
Irinotecan	liposome injection 4.3mg/mL	Onivyde®	Oncology	TBD	TBD	Upon Request

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Value added medicines

Product	Dosage Form	Indication	Status
Ramipril + Amlodipine + Atorvastatin	Tablets	Hypertension/Dyslipidemia	Available
Candesartan + Amlodipine + Atorvastatin	Tablets	Hypertension/Dyslipidemia	Upon Request
BlueOS02	Oral Thin Film	Multiple Sclerosis	Upon Request
BluEase03	Buccal spray	Erectile Dysfunction	Upon Request

Why **Bluepharma?**

- **DIFFERENTIATION & FOCUS ON CLIENT NEEDS**
- **INTEGRATED OFFER** (DEVELOPMENT, CLINICAL, MANUFACTURING, SALES)
- **PERFORMANCE AND TRACK RECORD**
- **FOCUS ON TIME TO MARKET**
- **RELIABILITY AND SUSTAINABILITY**

Create **value** through **Innovation.**

How? Contact us!

Bluepharma's facilities are **EU-GMP certified** and **approved by MFDS (Republic of Korea), ANVISA (Brazil), MOH Libya, SFDA (Kingdom of Saudi Arabia), Minpromtorg (Russian Federation) and by US FDA (2009, 2012, 2014, 2016, 2019).**

We are registered in **Iraq, Jordan, Kurdistan, Taiwan, UAE and Vietnam.**

EMAS GESTÃO AMBIENTAL VERIFICADA PT 000008

apcer CERTIFICADO ISO 14001 ISO 45001

IQNet CERTIFIED MANAGEMENT SYSTEM

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