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**PRODUCT
PORTFOLIO**

 **bluepharma**

Development and
Licensing Opportunities

Product Portfolio

Product	Dosage Form Strength		Reference Product	Basic Patent/ Regulatory Protection		Dossier Status	
				EU*	US		
🍽️ Alimentary Tract and Metabolism							
Prucalopride	tabs. 1mg, 2mg		Resolor® Motegrity®	-	-	Dossier Ready	📄
Sitagliptin	tabs. 25mg, 50mg, 100mg		Januvia®	-	-	Dossier Ready/ Approved	📋
Sitagliptin + Metformin	tabs. 50+500mg, 50+850mg, 50+1000mg		Janumet®	-	-	Dossier Ready/ Approved	📋
Vildagliptin	tabs. 50mg		Galvus®	-	-	Dossier Ready/ Approved	📋
Vildagliptin + Metformin	f.c. tabs. 50+500mg, 50+850mg, 50+1000mg		Eucreas®	-	-	Dossier Ready/ Approved	📋
⚙️ Anti-infectives for Systemic Use							
Azithromycin	f.c. tabs. 250mg, 500mg, 600mg		Zithromax®	-	-	Dossier Ready/ Approved	📋
Valganciclovir	f.c. tabs. 450mg		Valcyte®	-	-	Dossier Ready/ Approved	📋
🧬 Antineoplastic and Immunomodulating Agents							
Abiraterone	🟠ONConcept	tabs. 250mg	Zytiga®	-	-	Dossier Ready/ Approved	📋
Abiraterone	🟠ONConcept	f.c. tabs. 500mg	Zytiga®	-	-	Dossier Ready/ Approved	📋
Cabozantinib	🟠ONConcept	f.c. tabs. 20mg, 40mg, 60mg	Cabometyx®	09/2029 (PED¹)	09/2028 (ME)	Under Development	📄
Enzalutamide	🟠ONConcept	f.c. tabs. 40mg, 80mg, 120mg, 160mg	Xtandi®	06/2028 (SPC)	08/2027 (PAT)	Under Development	📄
Fingolimod	🟠ONConcept	caps. 0.25mg ⁽²⁾ , 0.5mg	Gilenya®	-	-	Dossier Ready/ Approved	📋
Ibrutinib	🟠ONConcept	f.c. tabs. 140mg, 280mg, 420mg, 560mg	Imbruvica®	04/2030 (PED¹)	05/2028 (PED)	Under Development	📄
Lenvatinib	🟠ONConcept	caps. 4mg, 10mg	Kisplyx® Lenvima®	04/2027 (PED¹)	04/2026 (PED¹)	Under Development	📄
Nilotinib	🟠ONConcept	caps. 50mg, 150mg, 200mg	Tasigna®	-	01/2024 (PED)	Dossier Ready	📄
Olaparib	🟠ONConcept	f.c. tabs. 100mg, 150mg	Lynparza®	09/2029 (PED¹)	04/2028 (PTE¹)	Under Development	📄
Palbociclib	🟠ONConcept	tabs. 75mg, 100mg, 125mg	Ibrance®	07/2028 (PED¹)	09/2027 (PED¹)	Under Development	📄
Palbociclib	🟠ONConcept	caps. 75mg, 100mg, 125mg	Ibrance®	07/2028 (PED¹)	09/2027 (PED¹)	Dossier Ready	📄

CPP | MA availability upon request. * - Germany used as reference. ¹ - Pending. ² - Upon Request.
 ME - Market Exclusivity. PAT - Patent. PED - Pediatric Exclusivity. PTE - Patent Term Extension. SPC - Supplementary Protection Certificate.
 - Partnership between Bluepharma, Helm and Welding.

Product Portfolio

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				EU*	US		
	Antineoplastic and Immunomodulating Agents						
Pomalidomide		caps. 1mg, 2mg, 3mg, 4mg	Imnovid® Pomalyst®	-	-	Dossier Ready	
Pazopanib		f.c. tabs. 200mg, 400mg	Votrient®	12/2025 (PED)	-	Dossier Ready	
Ruxolitinib		tabs. 5mg, 10mg, 15mg, 20mg, 25mg	Jakavi® Jakafi®	-	-	Under Development	
Sunitinib		caps. 12.5mg, 25mg, 37.5mg, 50mg	Sutent®	-	-	Dossier Ready/ Approved	
Tofacitinib IR		f.c. tabs. 5mg, 10mg	Xeljanz®	03/2028 (ME)	06/2026 (PED ¹)	Dossier Ready/ Approved	
Tofacitinib XR		e.r. tabs. 11mg, 22mg ⁽²⁾	Xeljanz XR®	03/2028 (ME)	06/2026 (PED ¹)	Under Development	
	Blood and Blood Forming Organs						
Eltrombopag		f.c. tabs. 12.5mg ⁽²⁾ , 25mg, 50mg, 75mg	Revolade® Promacta®	09/2025 (PED)	-	Dossier Ready	
Rivaroxaban		f.c. tabs. 2.5mg, 10mg, 15mg, 20mg	Xarelto®	04/2024 (PED)	02/2025 (PED)	Dossier Ready/ Approved	
	Cardiovascular System						
Amlodipine		tabs. 5mg, 10mg	Norvasc®	-	-	Dossier Ready/ Approved	
Ephedrine		injection 50mg/mL	Akovaz®	-	-	Dossier Ready/ Approved	
	Musculo-skeletal System						
Febuxostat		f.c. tabs. 80mg, 120mg	Adenuric® Uloric®	-	-	Dossier Ready/ Approved	
Penicillamine		caps. 250mg	Cuprimine®	-	-	Dossier Ready/ Approved	
	Nervous System						
Alprazolam		tabs. 0.25mg, 0.5mg, 1mg	Xanax®	-	-	Dossier Ready/ Approved	
Paroxetine		f.c. tabs. 20mg	Seroxat® Paxil®	-	-	Dossier Ready/ Approved	

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Other Available Dossiers

Product	Dosage Form Strength	Reference Product
 Alimentary Tract and Metabolism		
Acarbose	tabs. 50mg, 100mg	Glucobay®
 Anti-infectives for Systemic Use		
Ciprofloxacin	f.c. tabs. 250mg, 500mg, 750mg	Ciproxin® Cipro®
Clarithromycin	f.c. tabs. 250mg, 500mg	Klaricid® Biaxin®
Moxifloxacin	f.c. tabs. 400mg	Avelox®
 Blood and Blood Forming Organs		
Clopidogrel	tabs. 75mg	Plavix®
 Cardiovascular System		
Candesartan	tabs. 4mg, 8mg, 16mg, 32mg	Blopress® Atacand®
Candesartan HCTZ	tabs. 8+12.5mg, 16+12.5mg	Blopress Plus® Atacand HCT®
Droxidopa	caps. 100mg, 200mg, 300mg	Northera®
Ezetimibe + Simvastatin	tabs. 10+20mg, 10+40mg, 10+80mg	Vytorin® Inegy®
Irbesartan	f.c. tabs. 75mg, 150mg, 300mg	Approvel® Avapro®
Irbesartan HCTZ	f.c. tabs. 150+12.5mg, 300+12.5mg, 300+25mg	Coapprovel® Avalide®
Losartan	f.c. tabs. 12.5mg, 25mg, 50mg, 100mg	Cozaar®
Losartan HCTZ	f.c. tabs. 50+12.5mg, 100+25mg	Cozaar Plus®
 Musculo-skeletal System		
Nimesulide	tabs. 100mg	Aulin® Nimed®
 Nervous System		
Clonidine ER	e.r. tabs. 0.1mg	Kapvay®
Levetiracetam	f.c. tabs. 250mg, 500mg, 750mg, 1000mg	Keppra®
Levetiracetam	oral solution 100mg/mL	Keppra®

Complex Generics

Product	Dosage Form Strength	Reference Product	Indication	Dossier Status
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 Injectable

Amphotericin B	liposome injection 50mg/vial	Ambisome®	Fungal Infections	Upon Request	
Bupivacaine	liposome injection 13.3mg/mL	Exparel®	Postsurgical Analgesia	Upon Request	
Daunorubicin + Cytarabine	liposome injection 44mg+100mg/vial	Vyxeos®	Oncology	Upon Request	
Doxorubicin	liposome injection 2mg/mL	Caelyx® Doxil®	Oncology	Upon Request	
Irinotecan	liposome injection 4.3mg/mL	Onivyde®	Oncology	Upon Request	

 Nasal

Dihydroergotamine	nasal spray 4mg/mL	Migranal®	Migraine	Available	
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Value Added Medicines

Product	Dosage Form	Indication	Status
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Fixed-dose Combinations

Ramipril + Amlodipine + Atorvastatin	Tablets	Hypertension/Dyslipidemia	Available	
Candesartan + Amlodipine + Atorvastatin	Tablets	Hypertension/Dyslipidemia	Available	

Other Fixed-dose Combinations available upon request.

Oromucosal Delivery

BlueOS02	Oral Thin Film	Multiple Sclerosis	Upon Request	
BluEase04	Buccal Spray	Oral Mucositis	Upon Request	
Blue086	Oral Dispersible Tablet	Migraine	Upon Request	

Complex Steriles

BlueCI01	Liposome Injection	Rheumatoid Arthritis	Upon Request	
PEGASEMP™	Liposome Injection	Oncology	Upon Request	

Why Bluepharma?



Flexible Business Models



International Regulatory Expertise



Global Quality Certifications



Extensive and Differentiated Portfolio

Bluepharma's facilities are **EU-GMP certified** and **approved by:**

- US FDA (2009, 2012, 2014, 2016, 2019)
- SFDA (Kingdom of Saudi Arabia)
- ANVISA (Brazil)
- MFDS (Republic of Korea)
- Minpromtorg (Russian Federation)
- MOH Libya
- TMMDA (Turkey)

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



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