



ONConcept®

A STRATEGIC COLLABORATION IN THE FIELD OF ONCOLOGY



www.onconceptpharma.com





A strategic collaboration in the field of oncology

Three independent and certified European pharmaceutical companies - Bluepharma, Welding and Helm - united to form a leading partnership for **complex, differentiated and high potency products**.



Know-how, track-record and expertise

Combining their strengths, the **ONConcept®** alliance is providing:

- Large basket of oncology products and other products.
- Integrated solutions and services covering the full value chain.
- EU-based development and manufacturing site.
- Sound in-house scientific, regulatory and commercial expertise.
- International networks and global experience.
- Flexible adaptation to product- and customer-specific needs.



Development and
manufacturing site
8.000 m²





ONConcept®

Worldwide pharmaceutical corporations can now benefit from ONConcept's integrated offer.

ONConcept® is working on strategic alliances with multinationals and local companies for a basket of products. Rather than licensing one product at a time, the company will form long-term, multi-molecule alliances. ONConcept® will provide the full spectrum of its expertise and capabilities, oriented to serve the needs of its marketing partner, and work with the agility and flexibility to adjust to market or territory dynamics, for example with regard to time to market.

Forming the alliances will move ONConcept® toward its goal of being the partner of choice for oncology, supplied from Europe. In the coming years, the strategic alliance wants to become known as a reputable European supplier of highly potent drugs with the capabilities needed to develop, register, and supply complex products, ensuring competitiveness across the product lifecycle. In achieving that goal, ONConcept® will unlock major markets for its allies and help to expand access to life-changing medicines in Europe and beyond.



HIGHLY
POTENT
COMPLEX
PRODUCTS



ONConcept®

Product Basket

INN	Reference Product	Strength	Dosage Form	Indication
Abiraterone Acetate	Zytiga®	250mg, 500mg	Tablets	Prostate Cancer
Avatrombopag	Doptelet®	20mg	Tablets	Thrombocytopenia
Cabozantinib	Cabometyx®	20mg, 40mg, 60mg	Tablets	Renal Cell and Hepatocellular Carcinomas, Differentiated Thyroid Cancer
Eltrombopag	Revolade®/Promacta®	12.5mg, 25mg, 50mg, 75mg	Tablets	Thrombocytopenia, Severe Aplastic Anemia
Enzalutamide	Xtandi®	40mg, 80mg, 120mg, 160mg	Tablets	Prostate Cancer
Fingolimod	Gilenya®	0.25mg, 0.5mg	Capsules	Multiple Sclerosis
Ibrutinib	Imbruvica®	140mg, 280mg, 420mg, 560mg	Tablets	Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma, Waldenström's Macroglobulinemia, Mantle Cell Lymphoma ¹ , Chronic Graft-Versus-Host Disease ²
Lenvatinib	Lenvima®/Kisplyx®	4mg, 10mg	Tablets	Renal Cell, Hepatocellular and Endometrial Carcinomas, Differentiated Thyroid Cancer
Nilotinib	Tasigna®	50mg, 150mg, 200mg	Capsules	Chronic Myeloid Leukemia
Olaparib	Lynparza®	100mg, 150mg	Tablets	Ovarian, Breast, Pancreatic and Prostate Cancer
Palbociclib	Ibrance®	75mg, 100mg, 125mg	Tablets	Breast Cancer
Palbociclib	Ibrance®	75mg, 100mg, 125mg	Capsules	Breast Cancer
Pazopanib	Votrient®	200mg, 400mg	Tablets	Renal Cell Carcinoma, Soft Tissue Sarcoma
Pomalidomide	Imnovid®/Pomalyst®	1mg, 2mg, 3mg, 4mg	Capsules	Multiple Myeloma, Kaposi Sarcoma ²
Ruxolitinib	Jakavi®/Jakafi®	5mg, 10mg, 15mg, 20mg	Tablets	Myelofibrosis, Polycythemia Vera, Acute and Chronic Graft-Versus-Host Disease
Sunitinib	Sutent®	12.5mg, 25mg, 37.5mg, 50mg	Capsules	Gastrointestinal Stromal Tumor, Renal Cell Carcinoma
Tofacitinib	Xeljanz®	5mg, 10mg	Tablets	Rheumatoid and Psoriatic Arthritis, Ulcerative Colitis, Ankylosing Spondylitis, Polyarticular Course Juvenile Idiopathic Arthritis
Tofacitinib XR	Xeljanz XR®	11mg, 22mg	Tablets	Rheumatoid and Psoriatic Arthritis, Ulcerative Colitis, Ankylosing Spondylitis
Venetoclax	Venclyxto®/Venclexta®	10mg, 50mg, 100mg	Tablets	Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma, Acute Myeloid Leukemia

¹ Approved only by EMA. ² Approved only by FDA.

ONConcept®

Services

Pooling the complementary skills and competencies of Bluepharma, Welding and Helm, the **ONConcept®** covers the entire value chain - from portfolio building to product development and market supply.



Intellectual Property (IP) Support

- In-depth IP analysis by highly qualified, in-house team.
- Extensive experience in prosecution and challenge of IP.



API Sourcing

- API procurement based on over 60 years of experience.
- Global network of established partnerships and cooperations.



FDF Development, Manufacturing and Supply Chain

- EU-GMP approved unit, furthermore successfully inspected six times by USFDA (2009, 2012, 2014, 2016, 2019) as well as by MFDS (South Korea), MOHME Libya, SFDA (Saudi Arabia) and ANVISA (Brazil).
- Manufacturing within site inspected by authorities, GMP-approved and located in Portugal.
- Reliable and consistent supply from API and raw materials to commercial manufacturing.



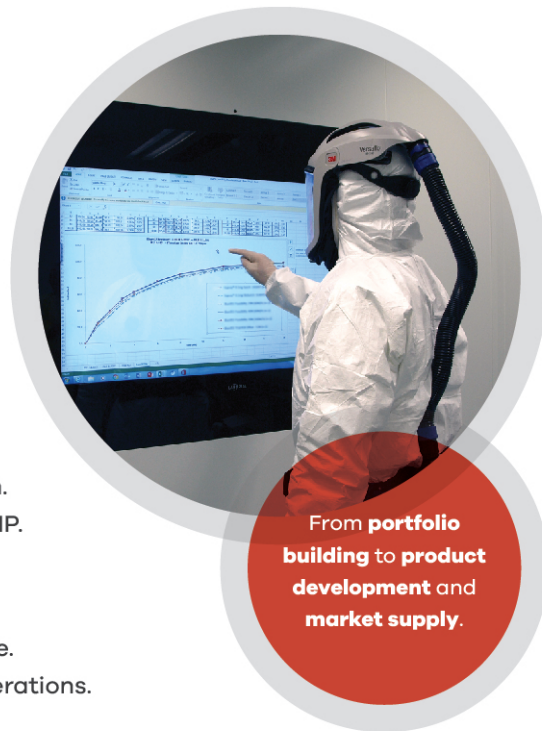
Clinical Development

- Development of clinical programs according to international standards by in-house experts.
- Conduct of clinical trials at European-based FDA-inspected CRO for Bioequivalence and Phase I studies.

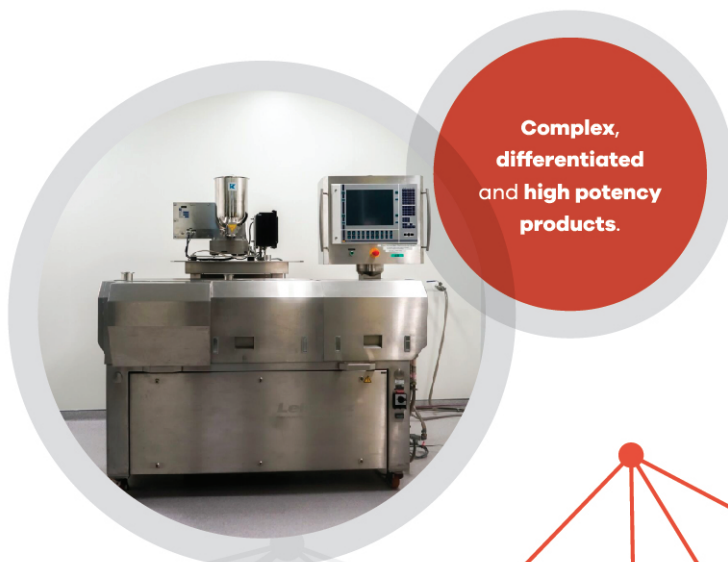


Regulatory Support

- Quick and smooth registration procedures according to latest EU/US requirements based on scientific and regulatory expertise.
- Professional CMC services and performance of all tasks from development stage to registered



From **portfolio building** to **product development** and **market supply**.



Complex, differentiated and high potency products.



YOUR VISION, OUR EXPERTISE

Be our commercial partner

Empower your portfolio and **consolidate your supply chain** through an attractive business model and exclusive commercial conditions.

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