



September 2020

Science for high quality biosimilars

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High-yield biosimilar development platform & partnered phase III lead asset

Low-risk
high potential
phase III
lead asset

- Xlucane (Lucentis® biosimilar) is a **low-risk** phase III lead asset
- Partnered with **STADA** and **Bausch + Lomb**
- Addressing a **€10.4b** market
- Expected to generate **+€100m in annual net-income** three years post **2022 launch**

Xlucane:
multiple near-
term triggers

- Sep/Oct 2020: Phase III fully recruited
- Q2 2021: Phase III top-line data
- Mid-2021: MAA/BLA filing
- Mid-2022: MAA/BLA approval

Robust pipeline
based on
proprietary
technology
platform

- Pipeline **biosimilar candidates addressing €8.7b** of originator sales
- Based on flexible, patented, **high-yield technology platform**

Biosimilars are similar to originator biologics, but with less risk

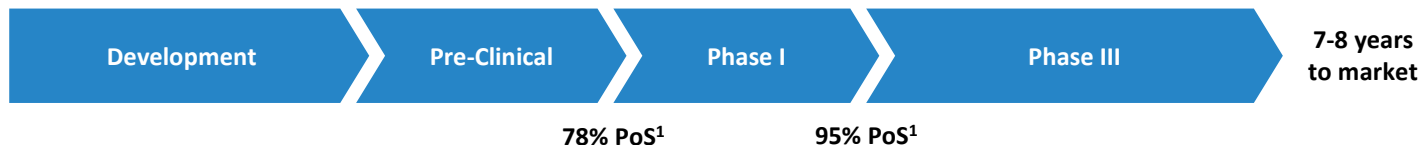
Biological drugs:

- Gene introduced into the cell, instructing it to produce target protein.
- Separation of the protein, which becomes the drug active substance.



Biosimilars:

- Gene instructing the cell to produce identical protein as originator, with the goal to demonstrate a highly similar effect.
- Result is a quicker road to market with less risk.



Portfolio targeting ~€12b in originator sales

Candidate / Product	Originator Product	Indication	Primary Patent Expiry	Global Annual Sales	Development Phase	Planned Launch	Commercialization Partner
Xlucane	Lucentis® (Roche)	Age related macular degeneration, Diabetic macular edema, Diabetic related retinopathy	2020 (US) 2022 (EU)	€3.6b	Ongoing Phase III	At patent expiry	 BAUSCH + LOMB
Xcimzane	Cimzia® (UCB)	Rhematoid arthritis, psoriatic arthritis, ankylosing spondylitis, psoriasis and Crohn's disease	2024 (US) 2025 (EU)	€1.7b	Pre-clinical	At patent expiry	Ongoing evaluation by STADA
Xdivane	Opdivo® (BMS)	Lung, liver, head & neck, kidney, colorectal cancer and melanoma	2026-30	€6.4b	Pre-clinical	At patent expiry	Ongoing evaluation by STADA
Xoncane	Oncaspar® (Servier)	Acute Lymphotic (all)	Expired	€0.2b	Pre-clinical		
Spherotide	Decapeptyl® (Debiopharm/Ipsen/Ferring)	Prostate cancer, Breast cancer, Endometriosis and Myoma	Expired	€0.4b	Pre-clinical		

€12.3b

Xlucane is a biosimilar to Lucentis® for treatment of severe eye diseases

Xlucane used in treatment of severe eye diseases

Wet age-related macular degeneration (“wAMD”) and Diabetes related macular oedema (“DME”)

Affected vision



Normal vision

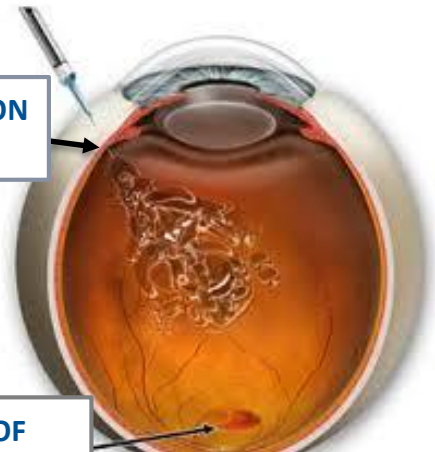


Leads to deterioration of vision and in worst case blindness

Xlucane binds to growth factor VEGFa

Binds to growth factor VEGFa and thereby inhibits growth of abnormal blood vessels causing the deteriorating vision

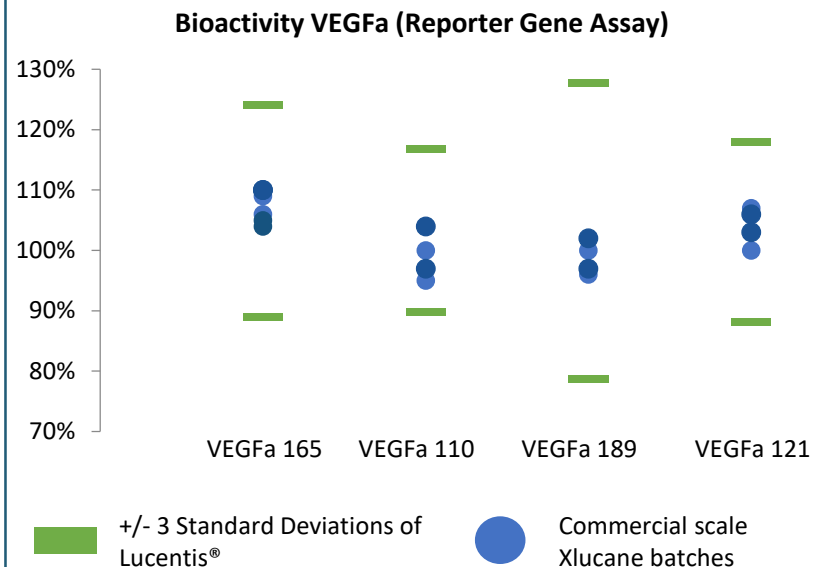
**INTRAVITREAL INJECTION
OF VEGFa INHIBITOR**



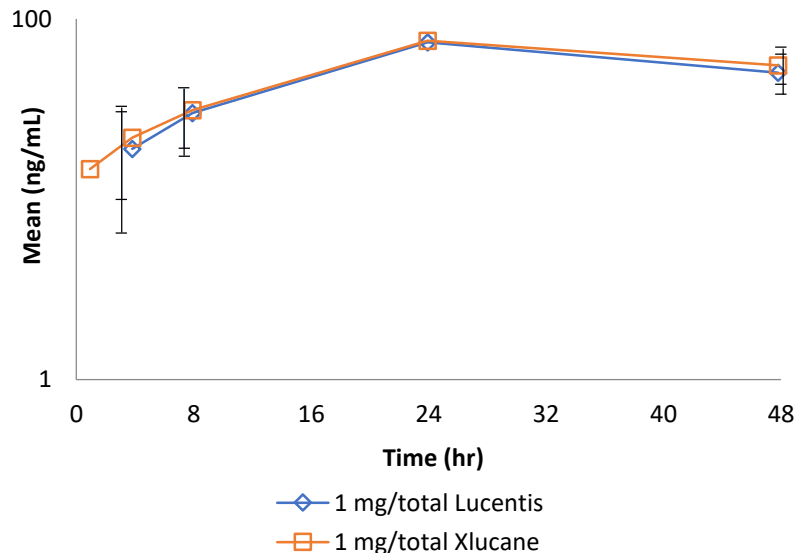
**INHIBITS GROWTH OF
ABNORMAL BLOOD VESSELS**

Xlucane binds to VEGFa equivalently to Lucentis®

Xlucane binds to VEGFa equivalently to Lucentis®



Xlucane demonstrates similar PK pattern *in vivo*



"The preliminary physicochemical and biological similarity assessment, confirms a high degree of biosimilarity. All defined acceptance criteria are met."

– EMA tailored scientific advice (February 2020)

Xplore: pivotal phase III to demonstrate equivalence of Xlucane vs Lucentis®

Xplore is a pivotal phase III equivalence trial



Xlucane
290 patients

Lucentis®
290 patients



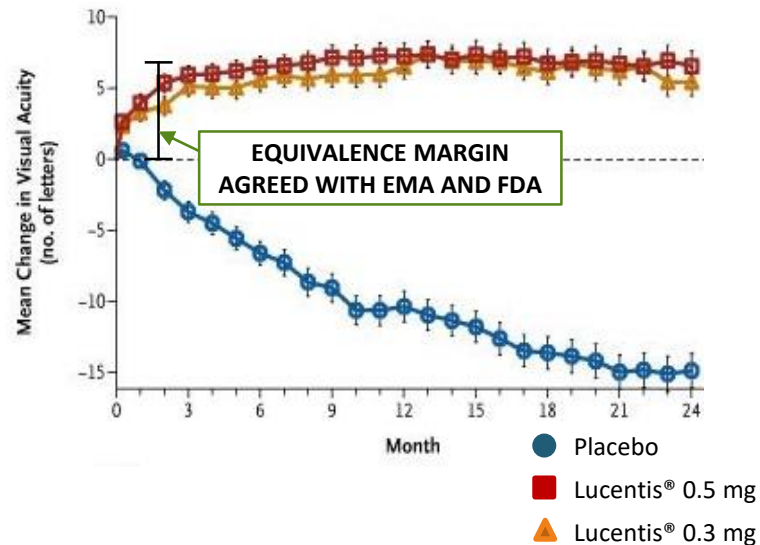
Week 8
Primary end-point



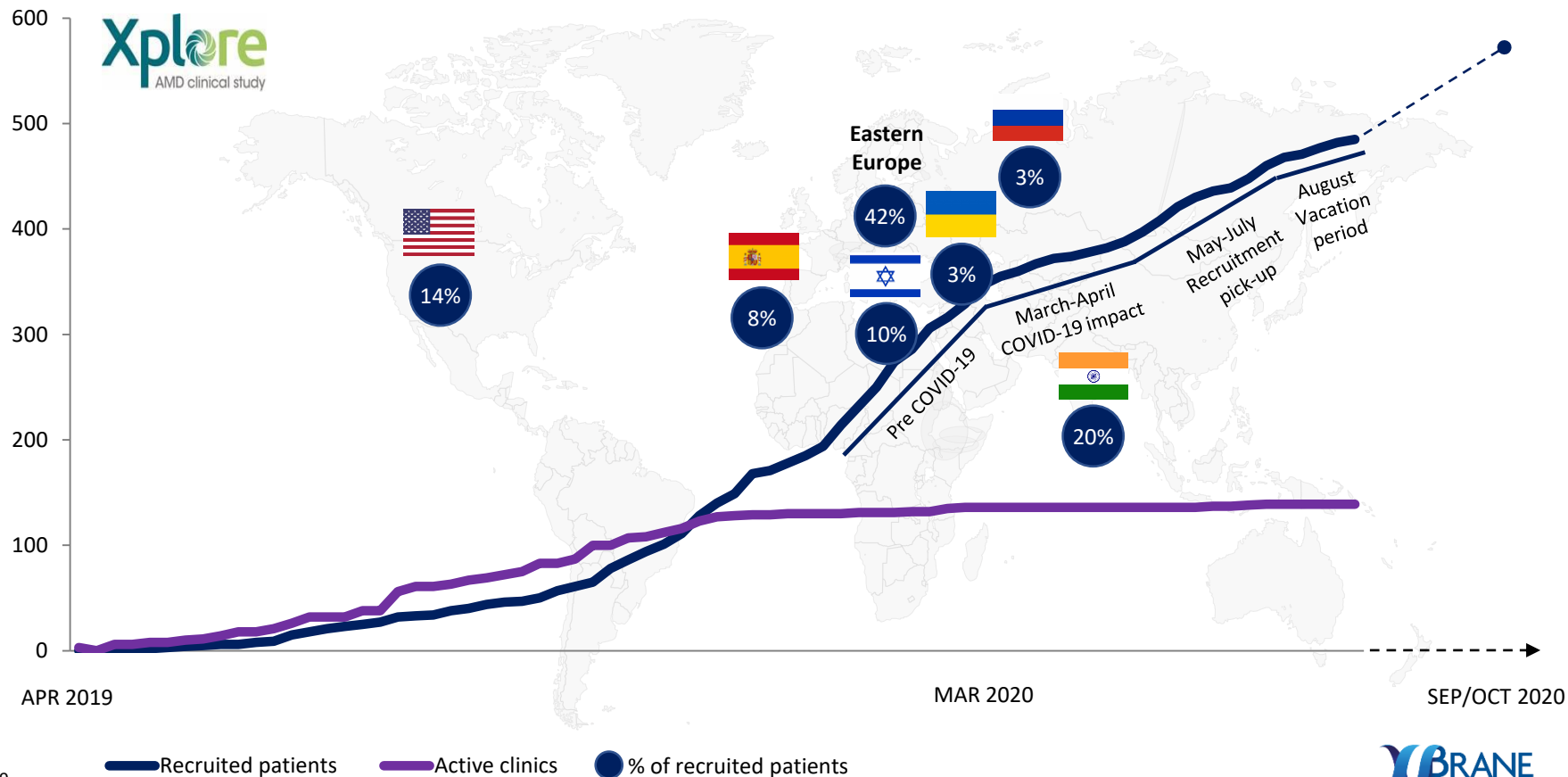
Week 52
End of treatment

Objective: demonstrate equivalence vs. Lucentis®

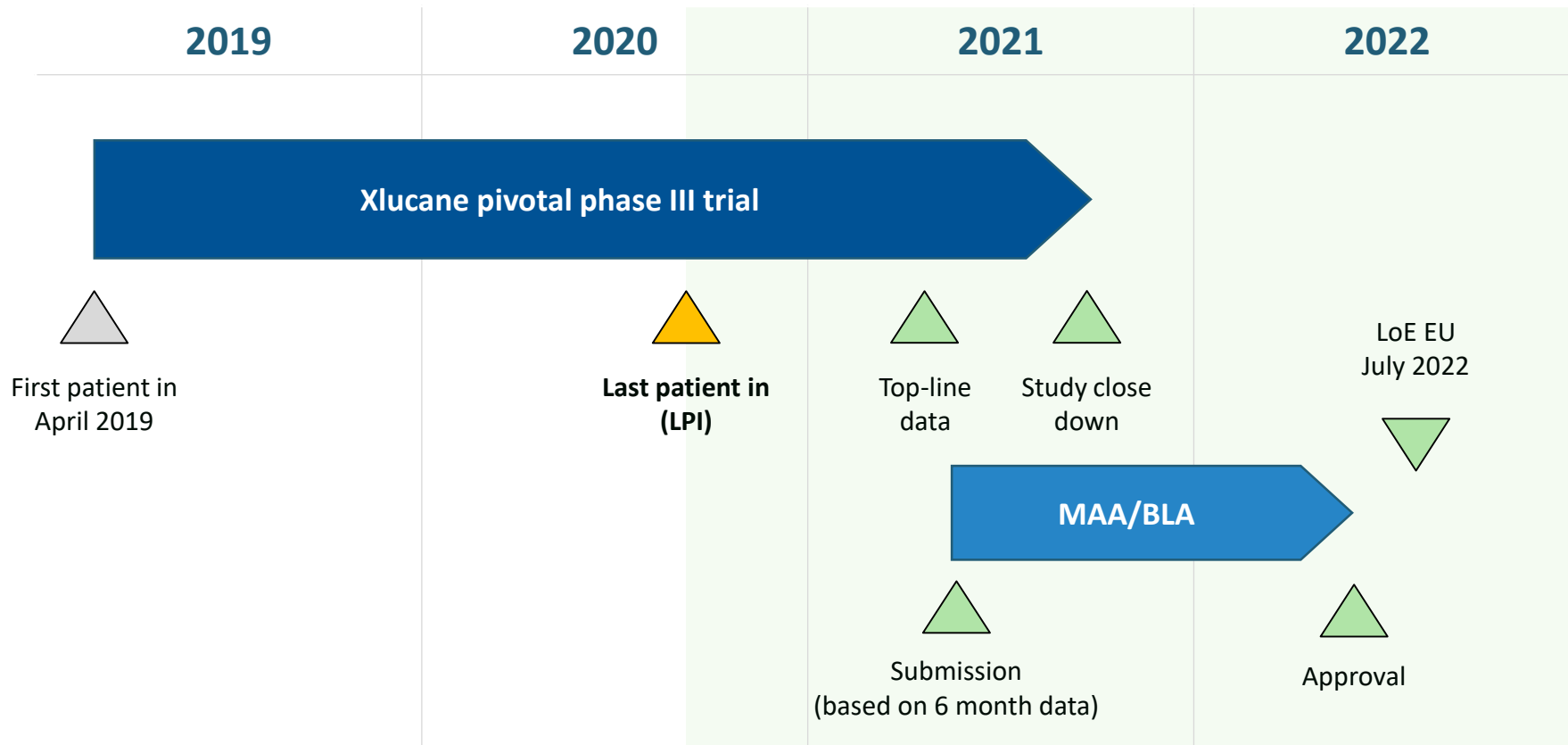
MARINA clinical trial (Lucentis® vs. placebo)



Xplore: ~85% of patients recruited as per mid-August 2020



Xlucane approval expected at Lucentis® loss of exclusivity mid-2022



Strong partners in place to commercialize Xlucane



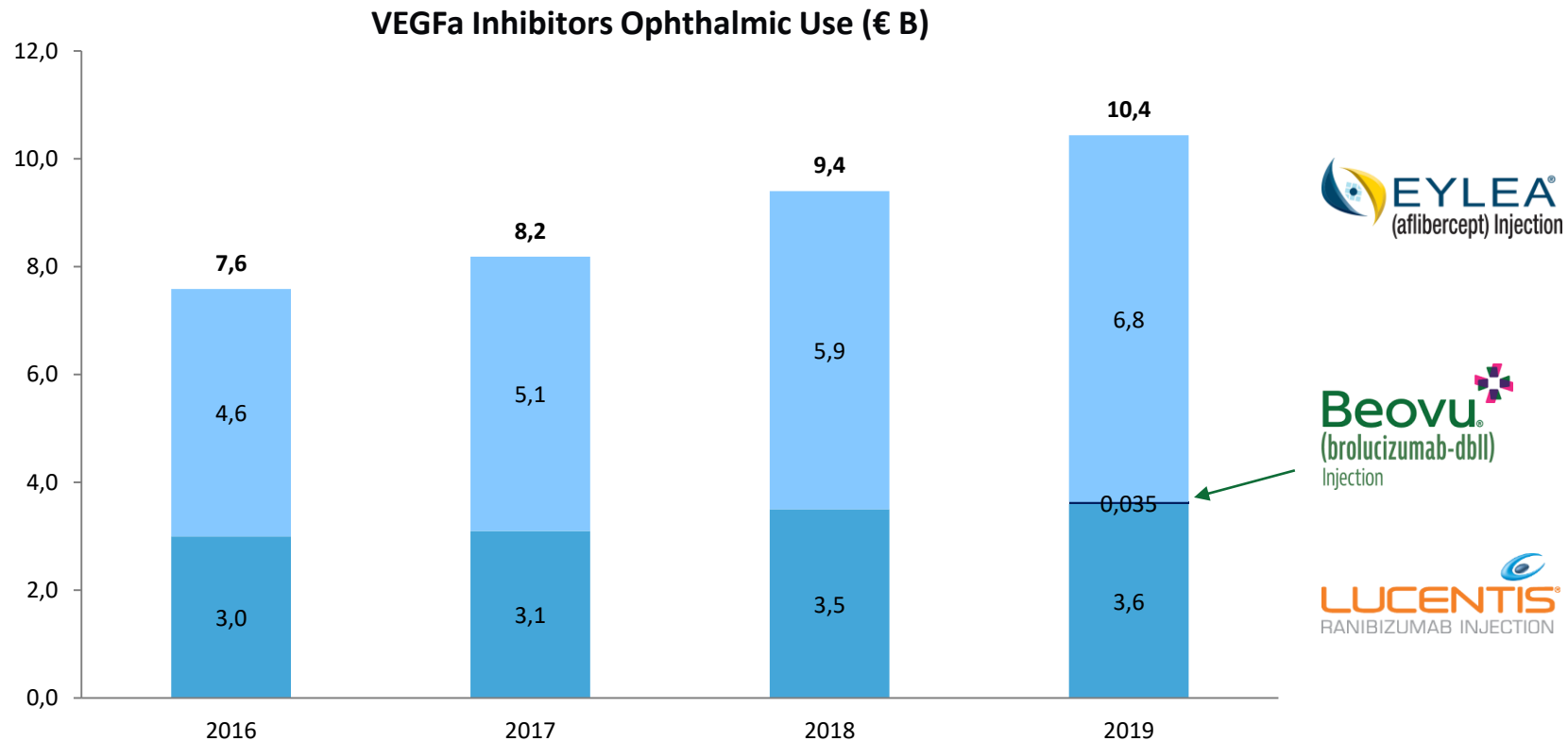
BAUSCH+LOMB

Profile	Biosimilar specialist with sales force and tender teams in place	Eye product and pharma specialist with existing specialist sales force with strong relationships to the 2.5K eye clinics in US prescribing Lucentis®
Territories	EU, MENA and select APAC countries	North America
Deal	Co-development deal with 50/50 development cost and profit split	- Mid single digit mUSD up-front, approval and launch milestones and profit share 50/50 share of all proceeds with STADA

Overview of Phase III Lucentis® biosimilar developers and their partners

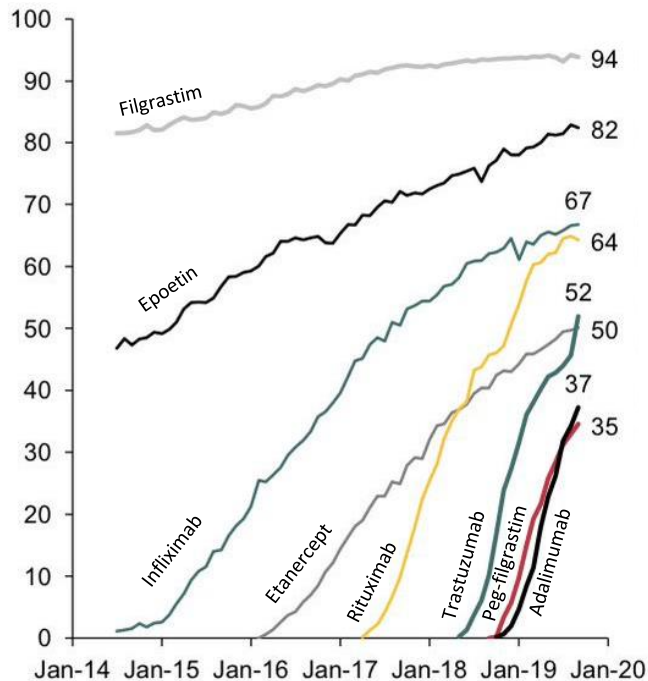
Developer	Partner & territories	Profile
		Biosimilar specialist
		Novel biologics and biosimilar specialist

Xlucane addresses a €10.4b market growing at 10% per year

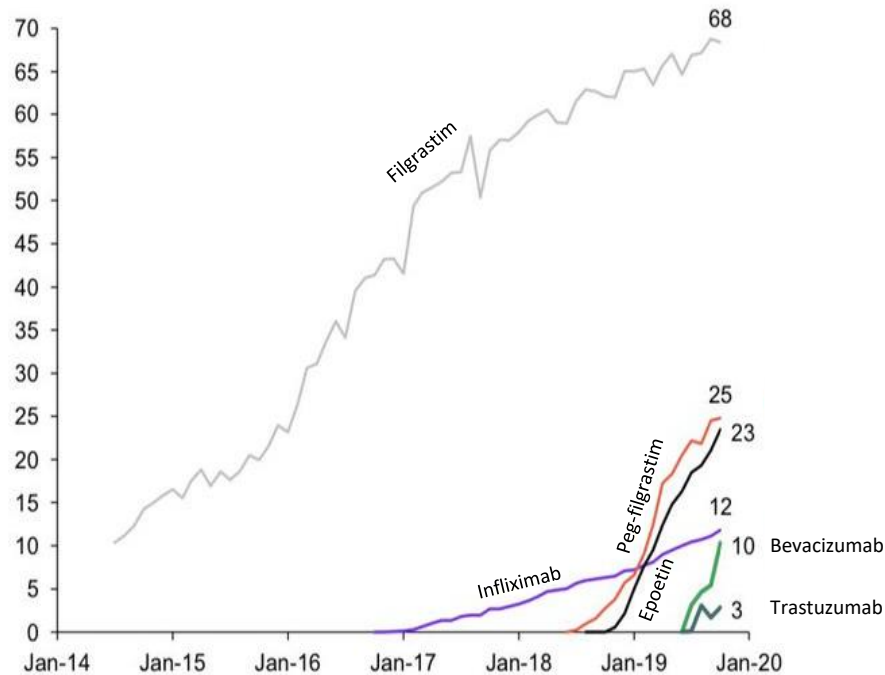


Rapid biosimilar uptake in both Europe and US

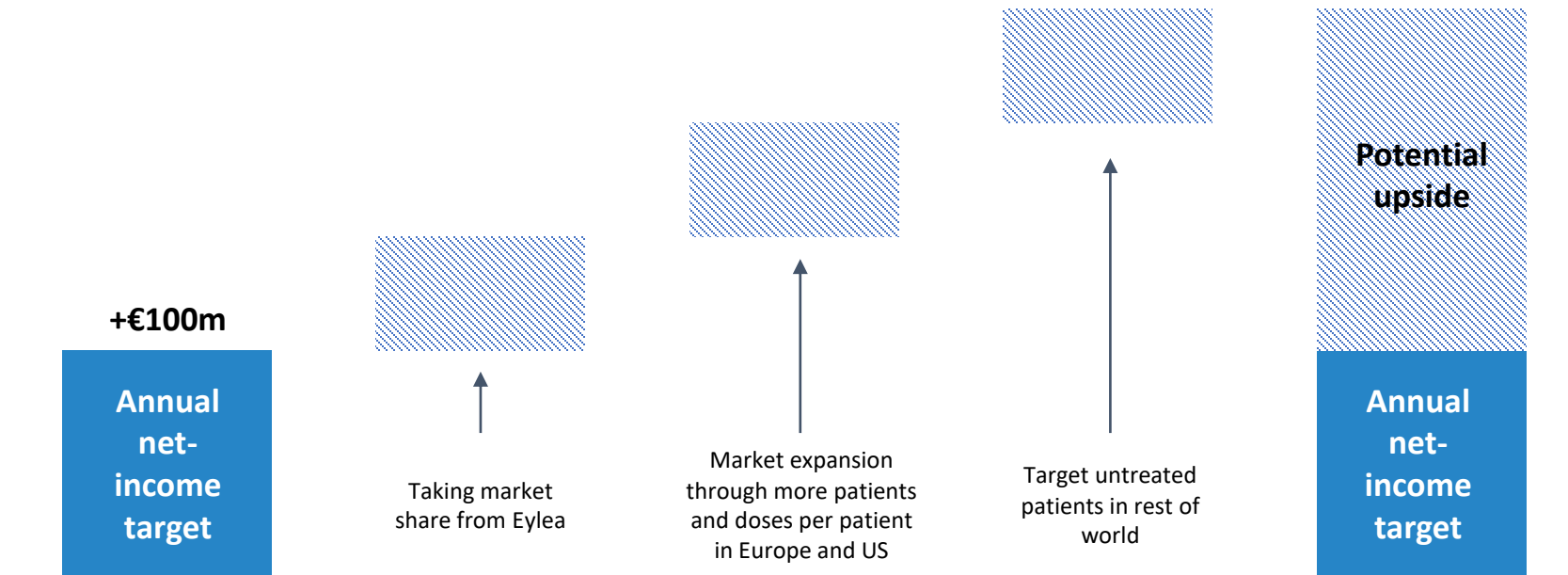
EU biosimilar market share (by standard units)



US biosimilar market share (by eaches)



Xlucane expected to generate net-income of +€100m three years after launch



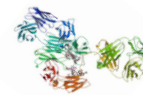
Xbrane leverages patented, low-cost platform technology



Gene



Cell



Protein

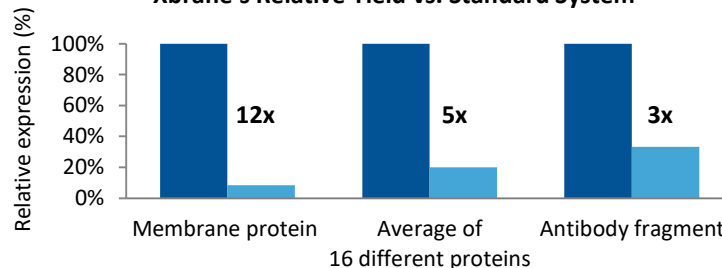
Xbrane platform technology

- Patented high yield *E.coli* gene construct (LEMO system)
- Ten new patent applications for both *E.coli* and CHO gene constructs
- Proprietary library of *E.coli* cell-lines
- Deep upstream and downstream process know-how In-house high quality analytical capabilities and equipment
- In-house high quality analytical capabilities and equipment

Benefits & achievements

- Up to 12x yield leading to +80% cost reduction for Drug Substance*
- Proprietary gene construct resulting in yield advantage for Xdivane in CHO cells (filed patent)

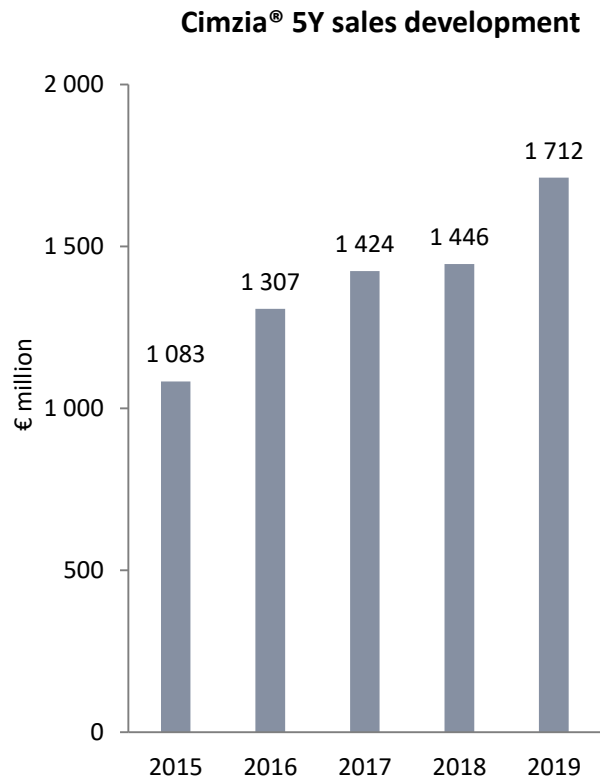
Xbrane's Relative Yield vs. Standard System



■ Xbrane technology (LEMO) ■ BL21(DE3)

Xcimzane – only biosimilar to blockbuster drug Cimzia®

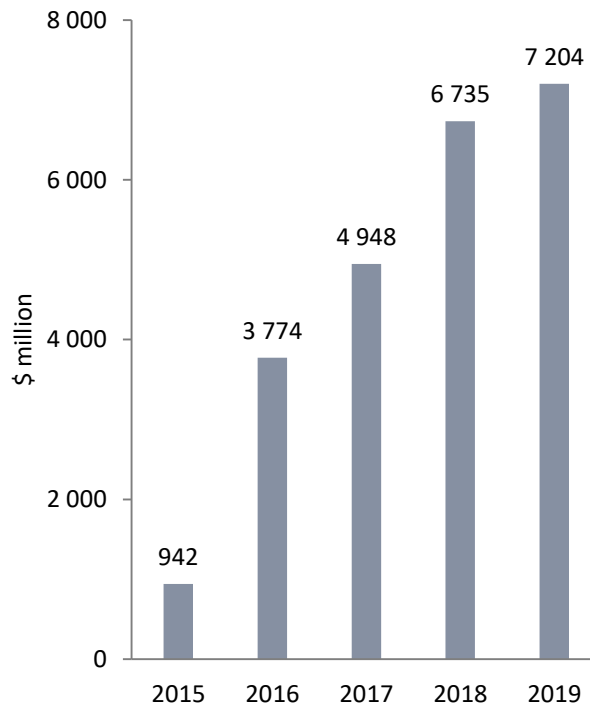
Xbrane Candidate	Xcimzane	Only known biosimilar candidate
Originator Product	Cimzia® (UCB) <i>TNF inhibitor</i>	Niche position
Indication	Rheumatoid arthritis, psoriasis, Crohn's disease, ankylosing spondylitis	Only product for women of child bearing age
Primary Patent Expiry	2024 (US) 2025 (EU)	Expected launch at patent expiry
Global Annual Sales (2019)	€1.7b	10% CAGR



Xdivane – frontrunner biosimilar to blockbuster drug Opdivo®

Xbrane Candidate	Xdivane	Frontrunner biosimilar program
Originator Product	Opdivo® (BMS) <i>PD-1 inhibitor</i>	Strong sales growth
Indication	Lung, liver, head & neck, kidney, colorectal cancer and melanoma	High medical need
Primary Patent Expiry	2026-2030	Xbrane launch at patent expiry
Global Annual Sales (2019)	\$7.2b	50% CAGR

Opdivo® 5Y sales development



Financial highlights

Cash and Cash Equivalents¹

SEK 232.5 M

Shares and Votes Outstanding¹

19,280,707

Directed Share Issue completed in May 2020 to new investors including TIN Fonder and Swedbank Robur Ny Teknik as well as existing investors including STADA and Swedbank Robur Medica.

Executive leadership team



Martin Åmark
CEO



Siavash Bashiri
COO



Susanna Helgesen
CFO



David Vikström
CTO



Anders Wallström
Head of Manufacturing &
Supply Chain



Dina Jurman
Head of Clinical Affairs



Maria Edebrink
Head of Regulatory
Affairs



Xiaoli Hu
Head of Business
Development



Board of directors



Anders Tullgren
Chairman



Eva Nilsagård
Director



Karin Wingstrand
Director



Mats Thoren
Director



Peter Edman
Director



Giorgio Chirivi
Director



Ivan Cohen-Tanugi
Director



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STO: XBRANE

