



# Formycon AG

## The Biosimilar Experts

April 2025

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## Skillset and mindset are our key ingredients



**Pure Play Biosimilar Company** – established 2012 in Munich, Germany.

Business model contains Income from **success payments and royalty streams**.



**250 employees** from more than 30 different countries.

More than **80%** of Formycon's workforce is engaged in **R&D activities**.



Combining high **professional expertise** in biopharmaceutical development **with agile mindset** enables Formycon to develop **multiple Biosimilar projects** in competitive timing and high quality.

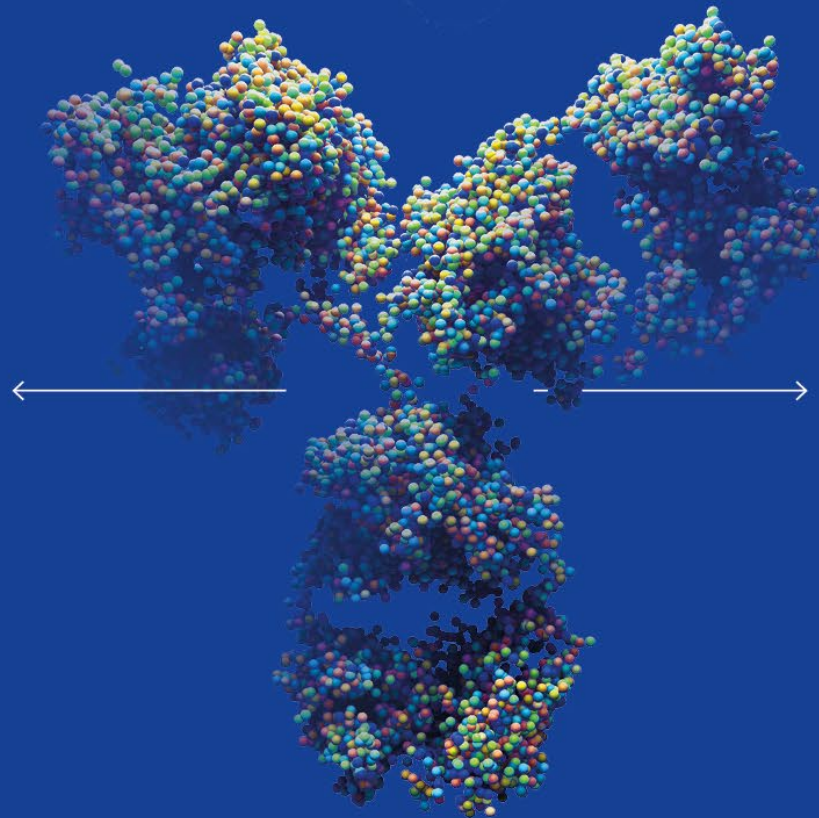


**Formycon's pipeline** includes **three approved biosimilars**, two of which are already launched in key global markets, as well as four biosimilar candidates in development.

**We are acting along a clear mission**

**Biosimilars open up enormous opportunities**

*Contributing to ease  
the **financial strains** on the  
world's healthcare systems*

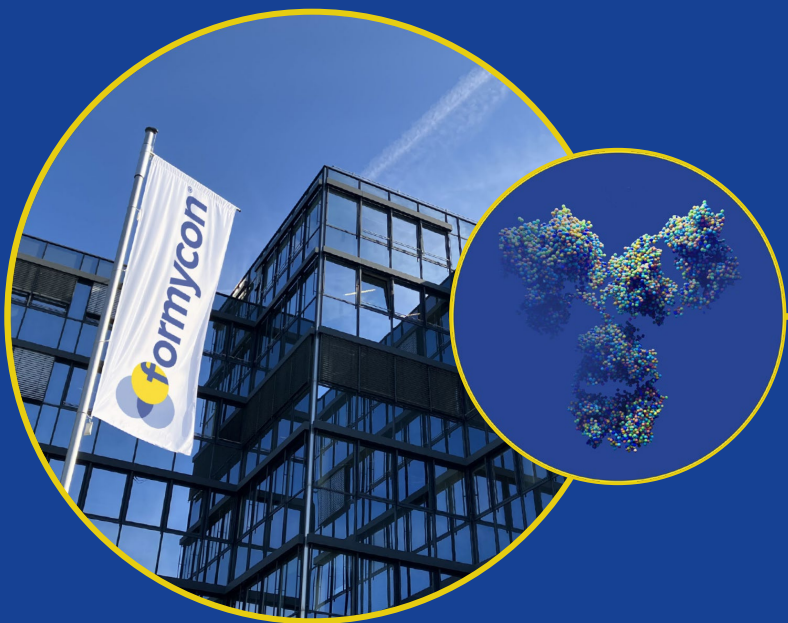


*Improving  
**patient access** to vital  
medicines*

# Laser focus on pipeline execution and expansion



## Maximizing our assets along a clear path



**2024**

Important year with many operational milestones successfully achieved

**2025**

Further transformation into a commercial company with two products on key global markets



Sustainable profitability with continuous pipeline growth

#TeamFormycon

Formycon

Biosimilar Experts

# Many important Milestones achieved over the last months



**FYB201**  
is so far launched  
in **20 Countries**  
worldwide


**FYB202**  
approved in  
**US and EU**




**FYB203**  
approved in  
**US...**  
... and as of January 2025  
also in the EU



**FYB206**  
Start of clinical  
development




**FYB210**  
Development  
start of new  
Biosimilar-Project




Formycon  
uplisted to  
**PRIME STANDARD**  
of Deutsche  
Börse

Formycon  
joins the **SDAX**  
and **TECDAX\*** of  
Deutsche  
Börse

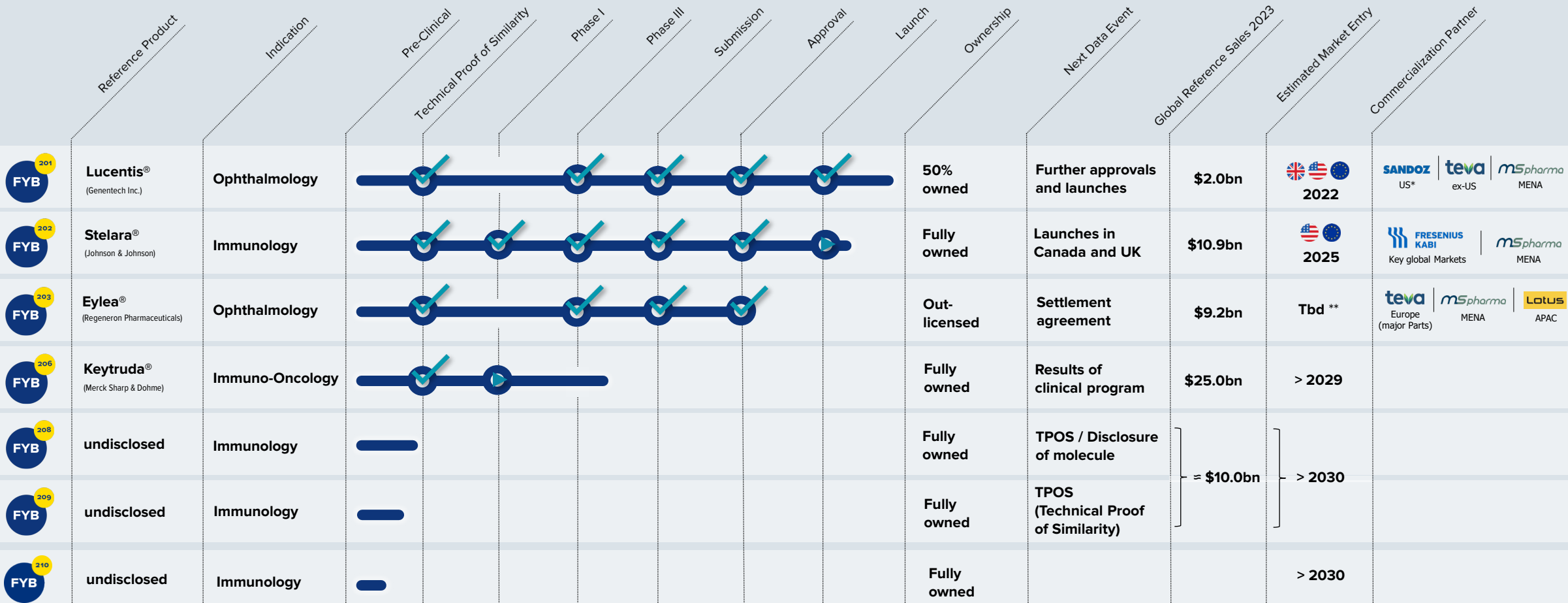


**FYB206**  
FDA allows  
Phase III Waiver\*\*



# Strong maturing and growing pipeline

## Diversified portfolio of commercial, late and mid stage programs



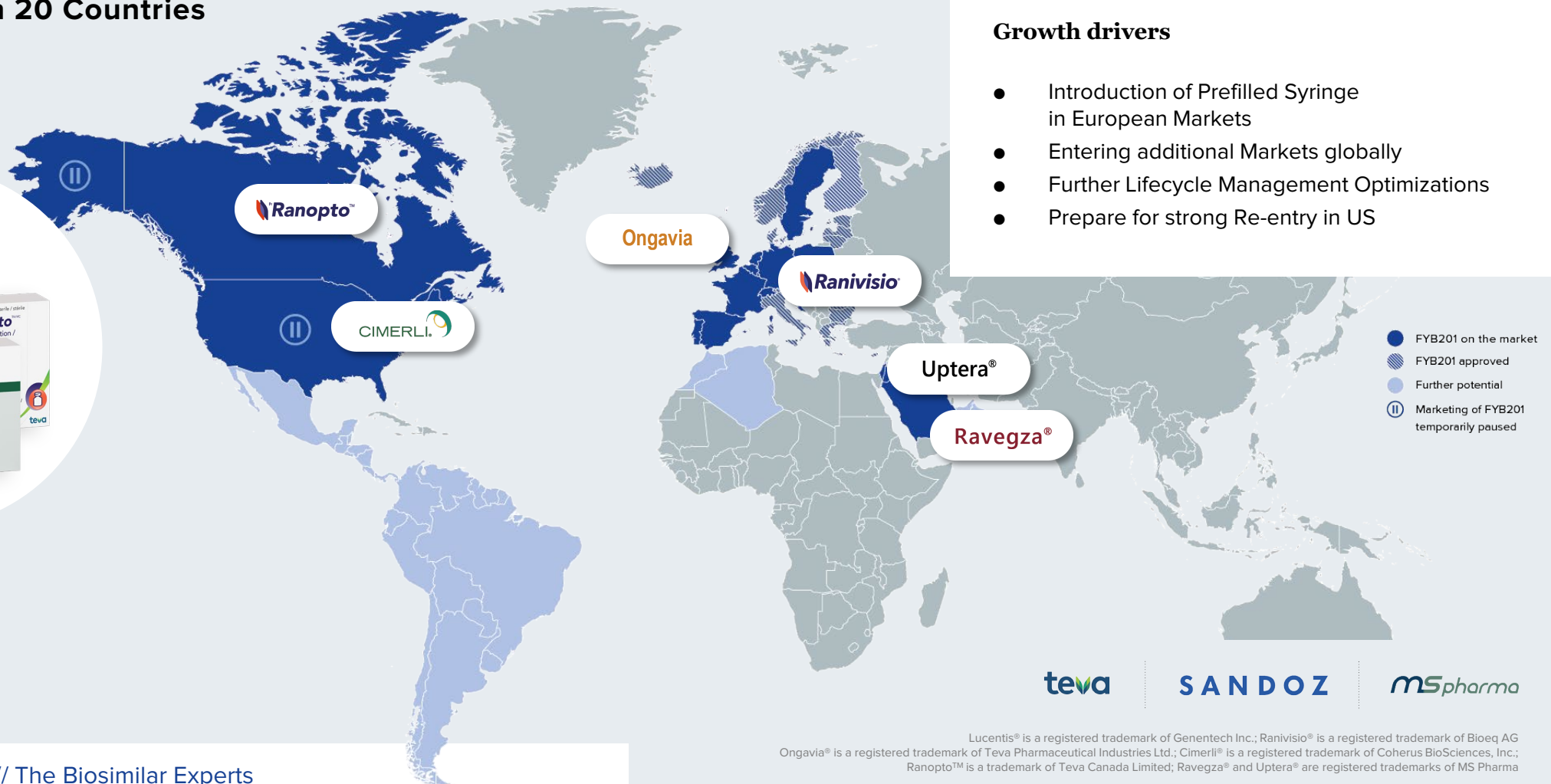
▶ ongoing ✓ completed

\*FYB201 US business was transferred from Coherus to Sandoz in March 2024

\*\*Depending on litigation progress

# Lucentis® Biosimilar FYB201 – Strong Presence across the World

FYB201/ranibizumab so far  
launched in 20 Countries



### Growth drivers

- Introduction of Prefilled Syringe in European Markets
- Entering additional Markets globally
- Further Lifecycle Management Optimizations
- Prepare for strong Re-entry in US

● FYB201 on the market  
 ▨ FYB201 approved  
 ● Further potential  
 ⏸ Marketing of FYB201 temporarily paused

teva

SANDOZ

MSpharma

Lucentis® is a registered trademark of Genentech Inc.; Ranivisio® is a registered trademark of Bioeq AG  
 Ongavia® is a registered trademark of Teva Pharmaceutical Industries Ltd.; Cimerli® is a registered trademark of Coherus BioSciences, Inc.;  
 Ranopto™ is a trademark of Teva Canada Limited; Ravegza® and Uptera® are registered trademarks of MS Pharma



# Lucentis® Biosimilar FYB201 (ranibizumab) well positioned



## Ranibizumab Competitive Landscape

Development Company	Commercialization Partner	Status Phase III	Submission / Approval
Samsung Biologics	Biogen	Completed (End of 2019)	Approved in US, EU, UK, CA, Launched in US & EU
<b>Formycon</b>	<b>Sandoz, Teva</b>	<b>Completed</b>	<b>Approved &amp; Launched in US, EU, UK, CA</b>
Xbrane / STADA	STADA (EU) / US to be settled	Completed (06/2021)	Approved & Launched in EU, Approved in UK, Re-submitted to FDA in January '25
Qilu Pharma	Own commercialization	Completed (EU-reference)	Approved in EU (01/2024)



# FYB202 – Stelara® Biosimilar launched in the U.S. and the EU



### Targeted Reference Indications

Psoriasis (Arthritis), Crohn’s Disease, Ulcerative Colitis

### Target Market 2024

USD 10.4 billion

### Project Rights

100% of project and commercialization rights

### Achievements:

- FDA- and EC-Approval for FYB202/Otulf® in Sept. 2024
- Launched in the U.S. and the EU in February resp. beginning of March 2025

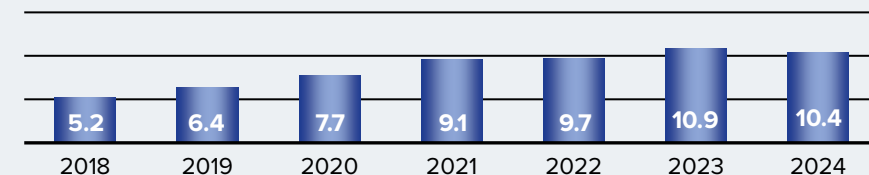
### Formycon Income Position

- Milestone payments related to the completion of clinical phases of about 25 million in H1 2023. Additional milestone payments upon approval in US and EU expected in late 2024 / early 2025 (estimated to total in the mid double digit million Euro).
- Post-commercialization value shared approximately equally by Formycon and Fresenius Kabi.

Commercial Partnership with  
Fresenius Kabi (Key Global Markets),  
MS Pharma (MENA/semi-exclusive)  
Semi-exclusive rights for Germany and  
Parts of LATAM remain with Formycon



### Stelara® Sales in USD billion



Stelara® is a registered trademark of Johnson & Johnson  
Otulf® is a registered trademark of Fresenius Kabi

# Stelara® Biosimilar Candidate FYB202 (ustekinumab)

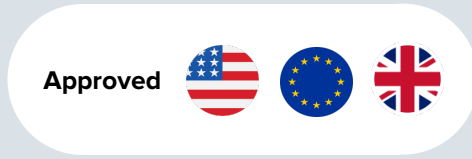


## Ustekinumab Competitive Landscape

Development Company	Commercialization Partner	Status Phase III	Submission / Approval
Alvotech	Teva (US) / Stada (EU)	Completed	Approved and Launched in EU / Approved in US Expected Launch in US: Feb.2025
Amgen	Own Commercialization	Completed	Approved and Launched in EU & US
Biocon	Own Commercialization	Completed	Approved and Launched in US / Approved in EU
Bio-Thera	Hikma (US)	Completed	--
Celltrion	Hikma (MENA)	Completed	Approved and Launched in EU / Approved in US Expected Launch in US: March 2025
<b>Formycon</b>	<b>Fresenius Kabi</b>	<b>Completed</b>	<b>Launched in the U.S. and the EU</b>
Meiji Selka Pharma & Dong A	Intas (Accord)	Completed	Approved in EU & US Expected Launch in US: May 2025
Samsung Bioepis	Sandoz	Completed	Approved and Launched in EU & US



# FYB203 – Eylea® Biosimilar approved in US and EU



## Targeted Reference Indications

Neovascular AMD<sup>1</sup>, DME<sup>2</sup>, mCNP<sup>3</sup>, RVO<sup>4</sup>

## Target Market 2024

USD 9.5 billion\*

## Project Rights

License Agreement with Klinge Biopharma GmbH (Royalty Model)

## Achievements and next important Milestones:

- FDA Approval FYB203 / AHZANTIVE® in June 2024
- EC Approval announced January 20, 2025
- UK Approval announced February 25, 2025
- Progress on litigation / settlement

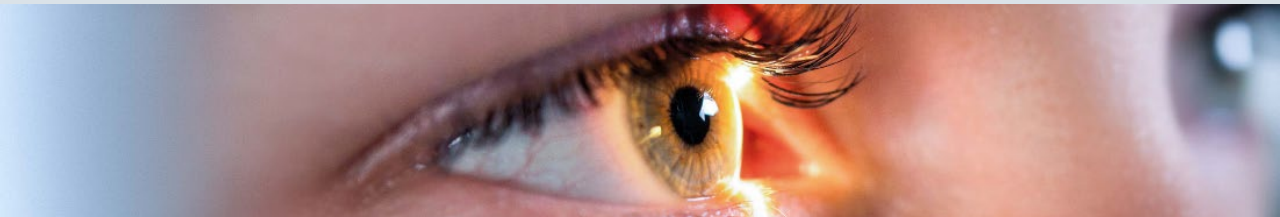
## Formycon Income Position

- Mid-single to low-double-digit-percentage participation in all Klinge income from commercialization partners across all territories.
- Income for managing the entire commercial supply chain of the finished product on behalf of Klinge

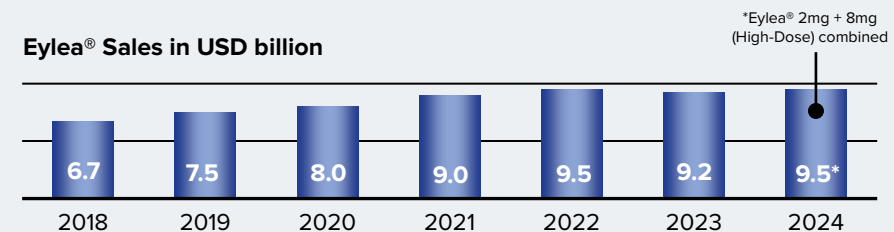
Commercial Partnership with  
**Teva** (EU/major parts; ISR), **MS Pharma** (MENA Region) and **Lotus** (APAC Region)



Eylea® is a registered trademark of Regeneron Pharmaceuticals Inc. AHZANTIVE® is a registered trademark of Klinge Biopharma GmbH



Eylea® Sales in USD billion



<sup>1</sup> Neovascular Age related Macular Degeneration Edema (nAMD),  
<sup>2</sup> Diabetic Macular Edema (DME),  
<sup>3</sup> Choroidal Neovascularization (CNV)  
<sup>4</sup> Macular Edema following Retinal Vein Occlusion (RVO)

# Eylea® Biosimilar Candidate FYB203 (aflibercept)



## Aflibercept Competitive Landscape

Development Company	Status Phase III	Submission / Approval
Alteogen	Completed	MAA submitted to EMA in Jul'24
Alvotech	Completed	ADVANZ file accepted by EMA in Dec '24
Amgen	Completed	Approved & Launched in US, CHMP approval received Jan '25
Biocon (Mylan / Momenta)	Completed	Approved in US & EU, CA settlement for Jul'25
Celltrion	Completed	Approved in EU
<b>Formycon</b>	<b>Completed</b>	<b>Approved in US &amp; EU</b>
Kidswell Bio & Chiome Bio	--	--
Samsung Bioepis	Completed	Approved in US & EU
SamChun Dang	Completed	--
Sandoz	Completed	Approved in US & EU



# FYB206 – Keytruda® Biosimilar Candidate in the leading group



## Targeted Reference Indications

Immuno-oncology: Melanoma (black skin cancer), non-small cell Lung Cancer, classical Hodgkin's Lymphoma and other Tumor Diseases

## Target Market 2024

USD 29.5 billion

## Project Rights

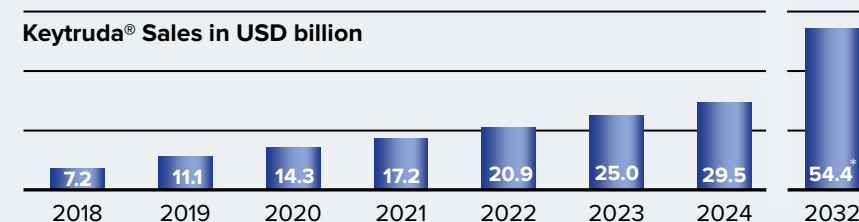
100% of project and commercialization rights

## Achievements and next important Milestones

- Important IP has been generated
- Clinical Phase I trial “Dahlia” started in June 2024 investigating the PK equivalence as part of a preventive therapy for patients who have had a malignant melanoma (black skin cancer) completely surgically removed
- After in-depth scientific dialogue and in consultation with the FDA, Formycon has come to the conclusion that the Phase III clinical trial initiated in July 2024 is no longer necessary for the development and approval of FYB206 in the U.S. In February 2025, we therefore announced that we will discontinue the Phase III trial.



Keytruda® Sales in USD billion



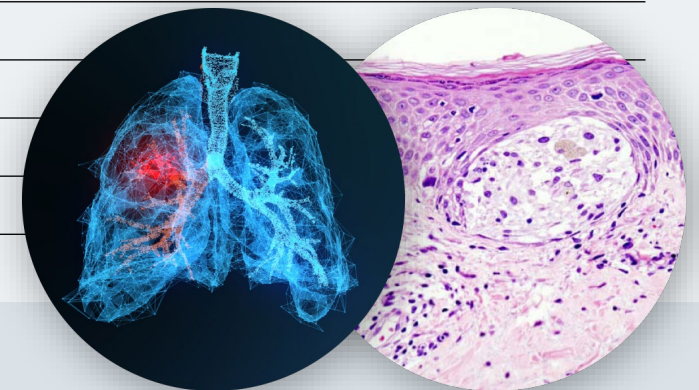
\*[www.custommarketinsights.com/report/keytruda-market/](http://www.custommarketinsights.com/report/keytruda-market/)  
Keytruda® is a registered trademark of Merck Sharp & Dohme LLC

# Keytruda® Biosimilar Candidate FYB206 (pembrolizumab)



## Pembrolizumab Competitive Landscape

Development Company	Status	Submission / Approval
ADvTECH	Pre-Clinical	--
Amgen	Phase I / III launched	--
Biocon	Pre-Clinical completed	--
Bio-Thera	Phase I / III launched	--
Celltrion	Phase I / III	--
Dr. Reddy's	Pre-Clinical completed	--
<b>Formycon</b>	<b>Phase I launched / No Phase III needed</b>	--
Henlius	Phase I / III launched	--
mABxience	Phase I / III launched	--
Quilu	Phase I & III launched	--
Sandoz	Phase I / III launched	--
Samsung Bioepis	Phase I & III launched	--



## Outlook for 2025 – the next operational and commercial milestones are coming soon



Approval of Stelara® Biosimilar FYB202/Otulf® in Canada



Approval of Stelara® Biosimilar FYB202/Otulf® in UK



Commercial Launch of Stelara® Biosimilar FYB202/Otulf®



Approval of Eylea® Biosimilar Candidate FYB203 in the EU



Approval of Lucentis® Biosimilar FYB201/Ranivisio® in LATAM



Commercialization Partnerships for Eylea® Biosimilar FYB203/Ahzantive® in further regions



Disclosure of Biosimilar Candidate FYB208



Launch of prefilled Syringe for Lucentis® Biosimilar FYB201



Commercialization Partnerships for Keytruda® Biosimilar Candidate FYB206



... and many more important milestones in the course of 2025



## Solid financial Performance as expected

Guidance  
2024

Revenue

55 to 65

€ million

EBITDA

-25 to -15

€ million

Adjusted  
EBITDA

-5 to +5

€ million

Working  
Capital

35 to 45

€ million

YE 2024

Revenue

69.6

€ million

EBITDA

-13.7

€ million

Adjusted  
EBITDA

-1.6

€ million

Working  
Capital

55.1

€ million

Guidance  
2025

Revenue

55 to 65

€ million

EBITDA

-20 to -10

€ million

Adjusted  
EBITDA

-20 to -10

€ million

Working  
Capital

25 to 35

€ million

Guidance 2025

Revenue:

- Revenues expected at 2024 level
- Development recharges continue decreasing by approx. 50%
- FYB202 Milestones and one time revenue 2024 replaced by royalties FYB202 and anticipated milestones FYB206

EBITDA:

- Expected at 2024 level
- Continuous investment in FYB208, FYB209 and FYB210
- Slight decrease in administrative expense anticipated

Adjusted EBITDA

- Expected below 2024
- At equity result expected to be zero as reduced profit shares expected due to reforming of US Market

Working Capital:

- Expected to be slightly below 2024
- Including partial draw down of shareholder loans

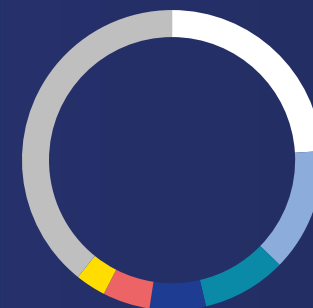
# Formycon – uplisted to Prime Standard and Part of the SDAX and the TecDAX



- **Market Segment:** Frankfurt Stock Exchange Regulated Market (Prime Standard)
- **Uplisted to Prime Standard on Nov. 12, 2024, part of the SDAX since Dec. 23, 2024, joined the TecDAX on Jan. 13, 2025,**
  - more **international Investors**
  - higher **Liquidity**
  - better **Transparency**
- **Registered capital: € 17,664,427**  
Shares outstanding: 17,664,427 (w/o par value)
- **Market price / Market capitalization: ~ € 500 million**
- **Member of Indices:** SDAX, TecDax, MSCI Europe Small Cap, MSCI EAFE IMI, MSCI Germany Small Cap

## Shareholder Structure

- **24.04 %** Santo Holding (Deutschland) GmbH
- **13.25 %** Wpart GmbH, Wen.Co Invest GmbH, Peter Wendeln
- **9.08 %** Gedeon Richter
- **6.04 %** Active Ownership
- **5.10 %** Detlef & Ursula Spruth
- **3.28 %** Stefan R.
- **39.21 %** Free Float\*\*



\*\* per definition of Deutsche Börse

## Research coverage:

- |                    |            |                           |                |
|--------------------|------------|---------------------------|----------------|
| – Berenberg        | <i>Buy</i> | – Metzler Capital Markets | <i>Buy</i>     |
| – First Berlin     | <i>Buy</i> | – M. M. Warburg           | <i>Buy</i>     |
| – Hauck Aufhäuser  | <i>Buy</i> | – mwb Research            | <i>Buy</i>     |
| – HC Wainwright    | <i>Buy</i> | – Oddo BHF                | <i>Neutral</i> |
| – Jefferies        | <i>Buy</i> | – Royal Bank of Canada    | <i>Buy</i>     |
| – Kepler Cheuvreux | <i>Buy</i> |                           |                |



## Fully focused pure-play Biosimilar Company



**WE HAVE** all ingredients to successfully develop and commercialize a growing pipeline



**WE ACT** in a highly attractive market



**WE CREATED** a strong Platform with track record



**WE ARE** entering the next stage of the Formycon Growth Story

## Formycon AG



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