Disclosures

Prof. Wojciech Jurczak, M.D., Ph.D.

Advisory Boards :

Sandoz Novartis, Roche, Celtrion, Janssen, Acerta, Astra Zeneca, Abbvie, TG Therapeutics, Takeda, NovoNordisk, Gilead, Servier

Research Funding:

Celgene, Abbvie, Gilead, TgTherapeutics, Janssen, Acerta,, Merck, Begene, Pharmacyclics, Pfizer, Roche, Sandoz – Novartis, Takeda, Teva, Servuier, Dova Pharmeceuticals, .

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Polska Unia Onkologii

Poland•East European Branch of I.C.O.S. International CardiOncology Society

Pratia YOUR SUPPORT IN CLINICAL TRIALS

mcm małopolskie centrum medyczne

European Medicines Agency Science Medicines Health

Centrum Onkologii – Instytut im. Marii Skłodowskiej-Curie

Leki biologiczne biorównoważne w hematologii – bezpieczeństwo, skuteczność, ekonomia

Prof. dr hab. n. med. Wojciech Jurczak
Centrum Onkologii – Instytut
Im. Marii Skłodowskiej - Curie

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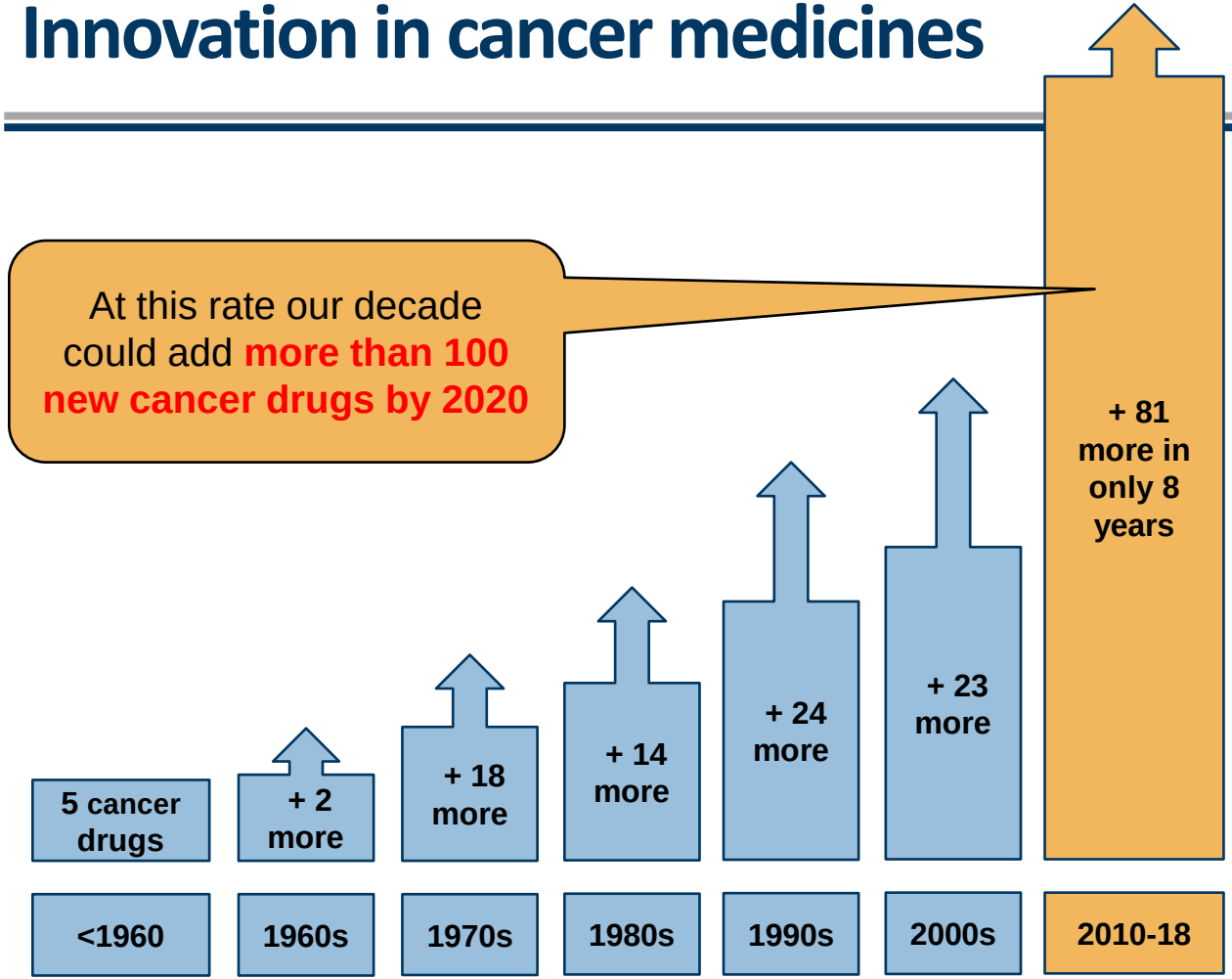
Innovation in cancer medicines



Good news for cancer treatment

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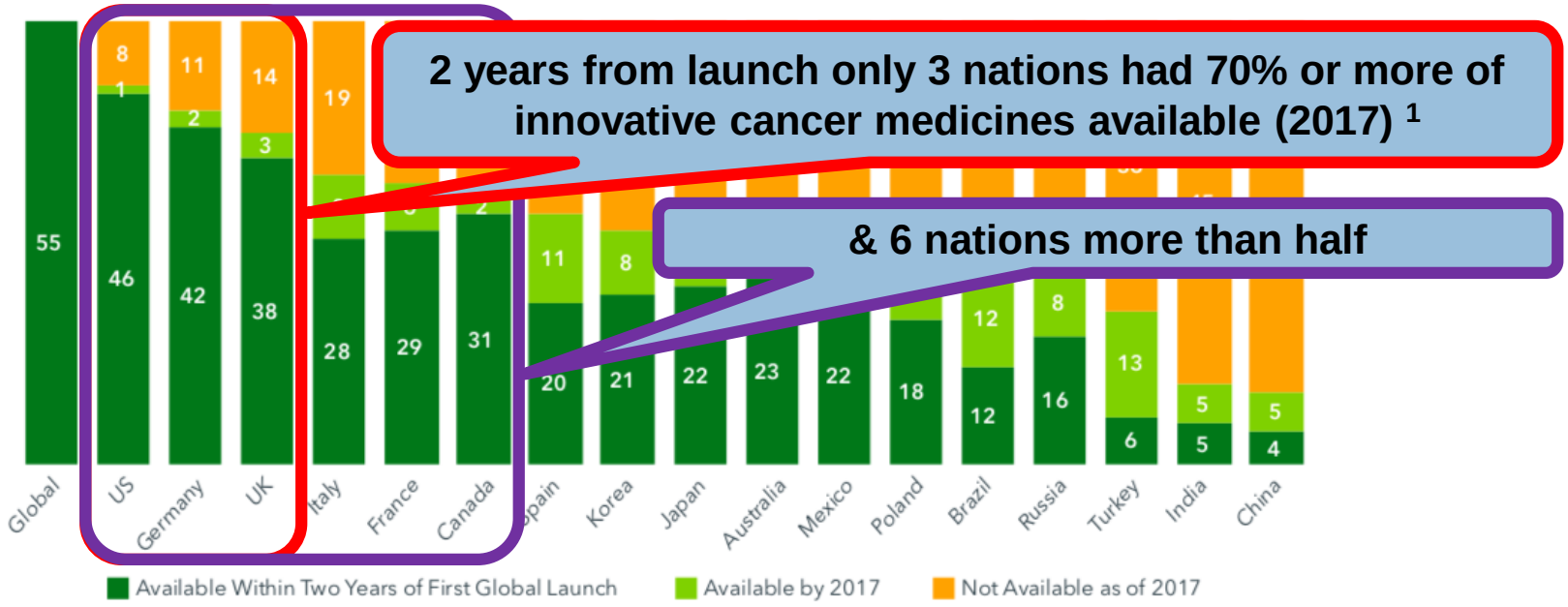
Health Economics

- The only medicine that works
- Is one that we can afford to use

Access to cancer medicines is a global problem



Only patients in the United States, Germany and United Kingdom have access to more than 40 of the 55 oncology medicines initially launched between 2012 and 2016, due to manufacturers not filing for regulatory approval, delays or denials of approval, or manufacturers awaiting the results of reimbursement negotiations prior to launching the drug in the country.

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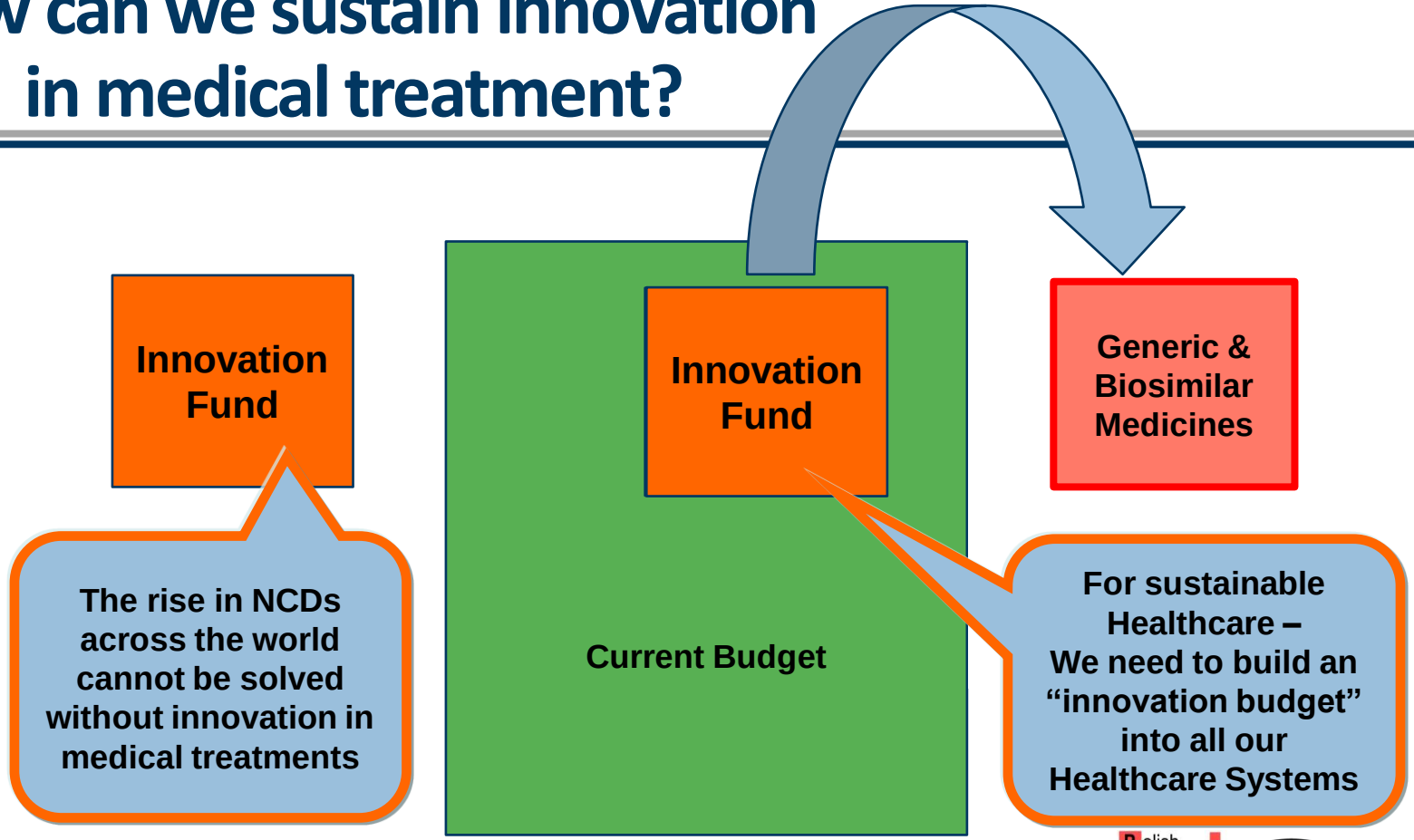
Access to cancer medicines is a global problem

Only patients in the United States, Germany and United Kingdom have access to more than 40 of the 55 oncology medicines initially launched between 2012 and 2016, due to manufacturers not filing for regulatory approval, delays or denials of approval, or manufacturers awaiting the results of reimbursement negotiations prior to launching the drug in the country.

How can we sustain innovation in medical treatment?



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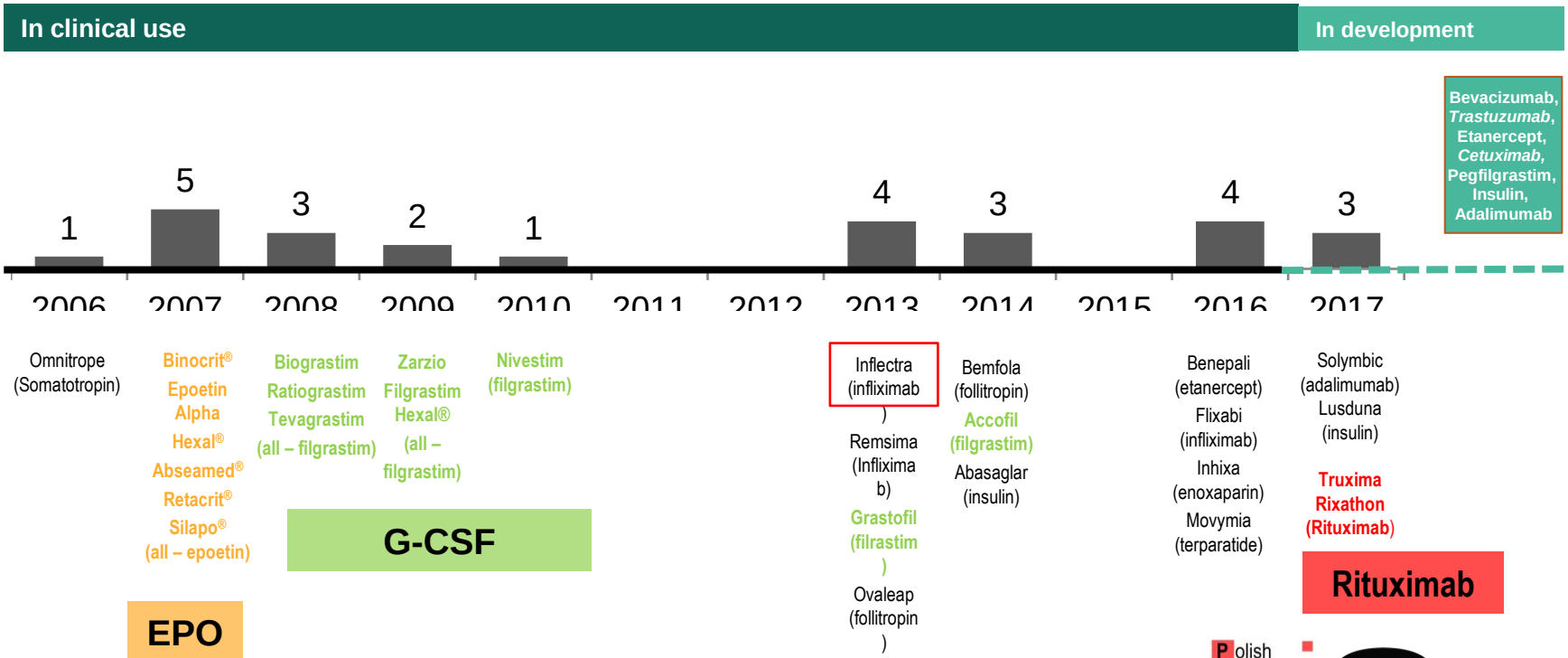
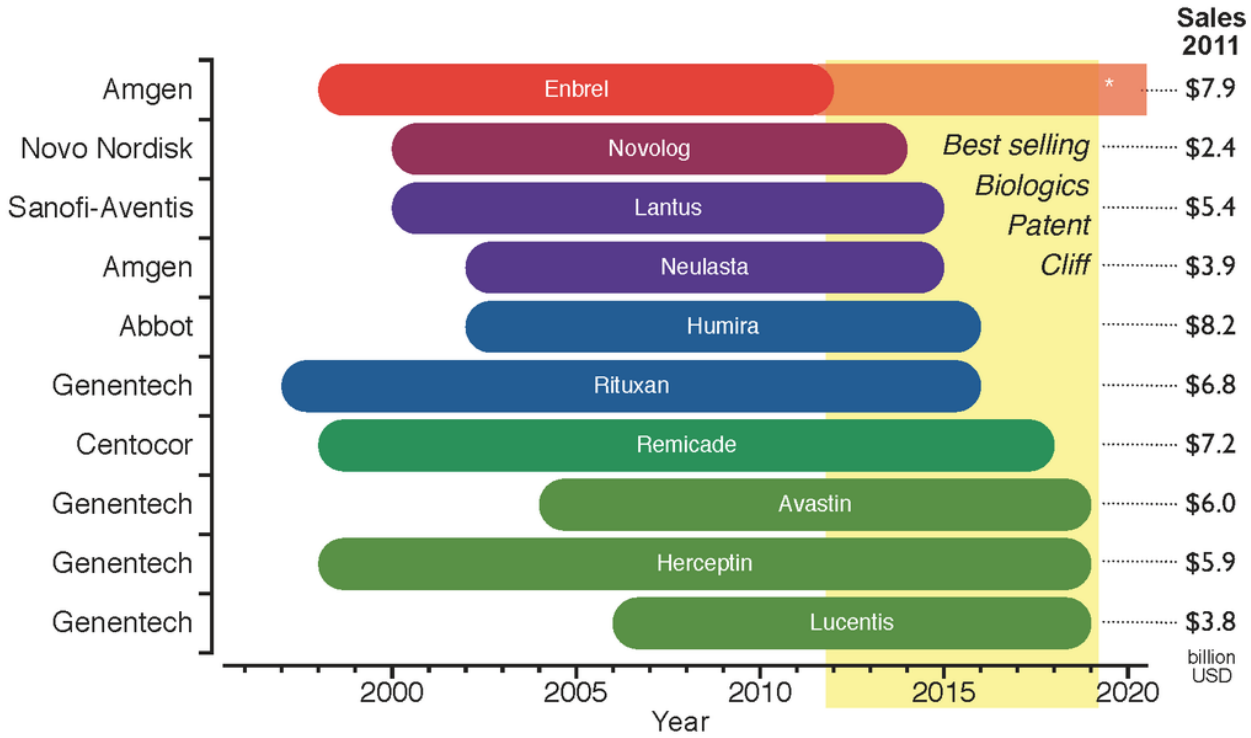
Biosimilars Approved by EMA



G-CSF: Granulocyte-colony stimulating factor; EMA: European

Biosimilars which may be potentially developed in the next 10 years



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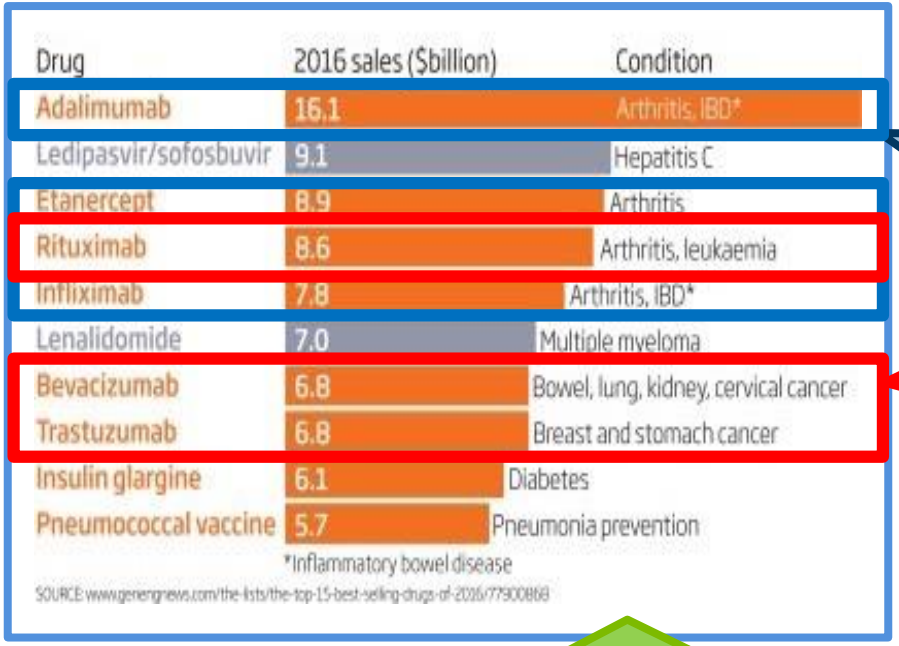
The future of medicines budgets

- More patients to treat
- More treatments for patients
- Means higher costs



4 of the top 10 are biologics for Inflammatory Disease

3 of the top 10 are biologics for Haematology & Oncology

8 of the world's top 10 selling medicines are biologics

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The future of medicines budgets

7 of those 10 have, or will soon have biosimilar brand competition

In 2016 sales of these 7 totaled $61.1 Billion USD

Potential 33% price savings gives back >$20 Billion USD a year to sustain global healthcare

4 of the top 10 are biologics for Inflammatory Disease

3 of the top 10 are biologics for Haematology & Oncology

8 of the world's top 10 selling medicines are biologics

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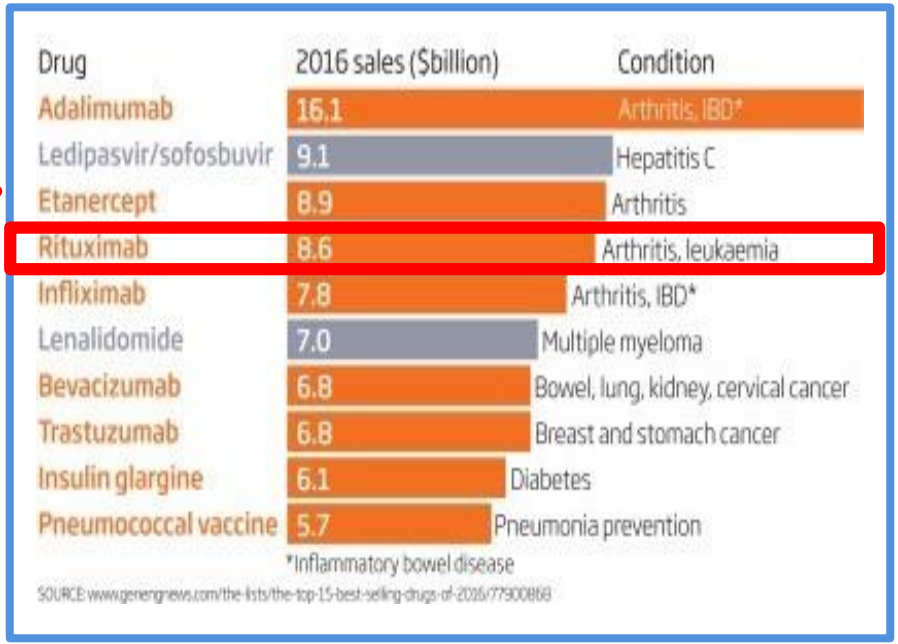
Biosymilary Rituksymabu w Polsce

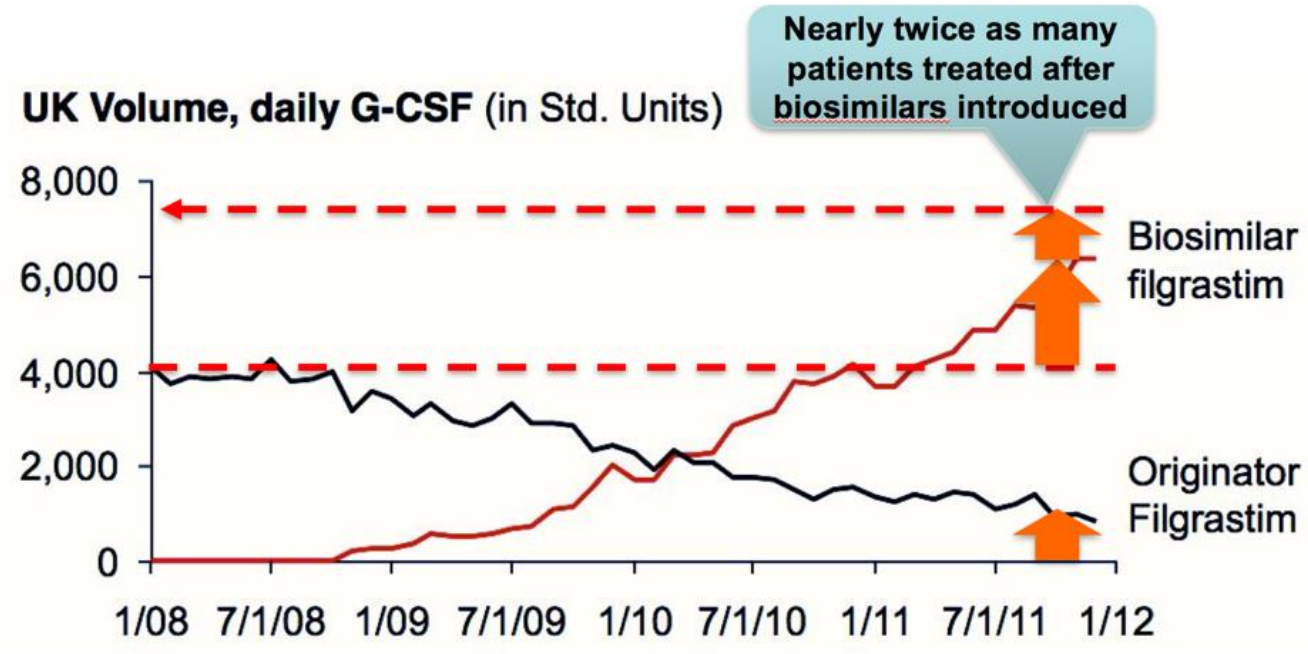
Biosymilar Rituximabu dostępny w Polsce od 2019

W 2019 – koszt 225 mln PLN

Od 2020 oszczędności 90 – 140 mln PLN



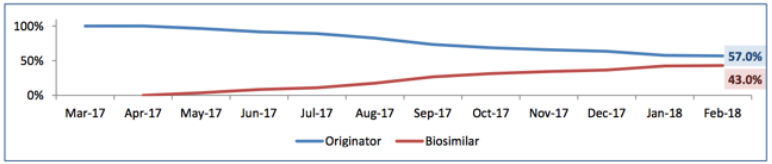
After intruducing G-CSF biosymilar it's usage doubled



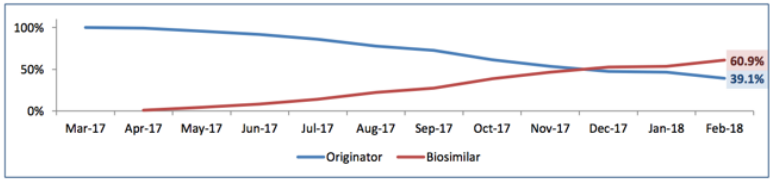
Walsh K.: Biosimilar Medicines 11th EGA International Symposium, 2013

Truxima & Rixathon achieved a very fast biosimilar penetration throughout Europe

Volume market share

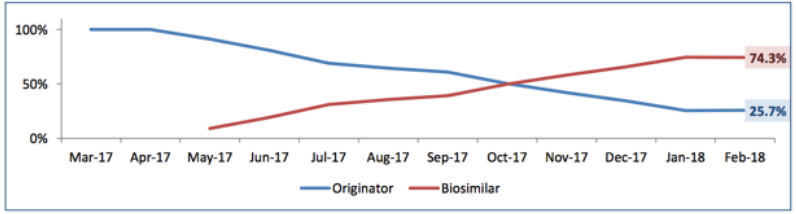


Germany

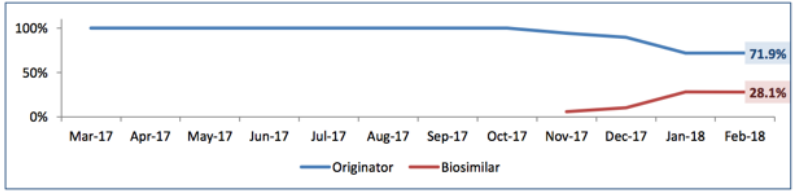


UK

Volume market share



Netherlands



Austria*

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MoAb in NHL: Everything Started With Rituximab


Coiffier,

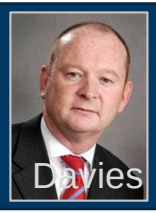
Czuczman,

Sales,

Marcus,

Hiddemann

Development and registration of original particle (Roche)


Davies

Subcutaneous Rituximab (Roche)


Coiffier,

Jurczak

Rituximab biosimilars:

- **CT-P10 (Celltrion)**
- **GP2013 (Sandoz Novartis)**

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Rituximab Biosimilars were registered by EMA in 2017

Research on Biosimilars: pivotal trials and principles
Wojciech Jurczak, Arnold G Vulto, Jutta Amersdorffer, Won S Kim, Bertrand Coiffier
The Lancet Haematology, Vol. 4, No. 9, e409–e410 Published: September, 2017

Rituximab biosimilar and reference rituximab in patients with previously untreated advanced follicular lymphoma (ASSIST-FL): primary results from a confirmatory phase 3, double-blind, randomised, controlled study
Wojciech Jurczak, Ilídia Moreira, Govind Babu Kanakasetty, Eduardo Munhoz, Maria Asunción Echeveste, Pratyush Giri, and others
The Lancet Haematology, Vol. 4, No. 8, e350–e361Published: July 13, 2017

Rituximab biosimilars: introduction into clinical practice
Shinichi Makita, Kensei Tobinai
The Lancet Haematology, Vol. 4, No. 8, e342–e343 Published: July 13, 2017

Efficacy, pharmacokinetics, and safety of the biosimilar CT-P10 compared with rituximab in patients with previously untreated advanced-stage follicular lymphoma: a randomised, double-blind, parallel-group, non-inferiority phase 3 trial
Won Seog Kim, Christian Buske, Michinori Ogura, **Wojciech Jurczak**, Juan-Manuel Sancho, Edvard Zhavrid, and others
The Lancet Haematology, Vol. 4, No. 8, e362–e373 Published: July 13, 2017

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Medicines regulation can seem complex: Variability in structure can be acceptable

- Which key will open the lock?

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How similar are biosimilars and their reference medicines in biochemical structure?

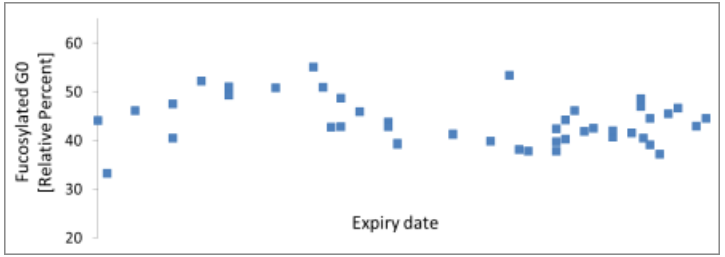
✓ **Amino acid sequence** **Primary Sequence**	**Identical**
✓ **Folding** Secondary, tertiary, quaternary structure	**Indistinguishable**
✓ **Glycosylation and related substances**	**Identical structures in comparable amounts** Differences are only acceptable if they are clinically not relevant
✓ **Biological functions**	**Comparable**

Variability in glycosylation and related substances is in the nature of biologicals

Batch-to-batch

- Non-identicality is a normal principle in glycosylated proteins
- No batch of any biologic is ‘identical’ to the other batches
- Variability is tightly controlled within acceptable limits

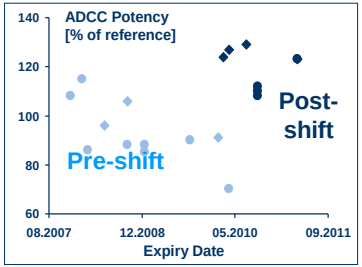
Variability of major glycan variant in commercial mAb

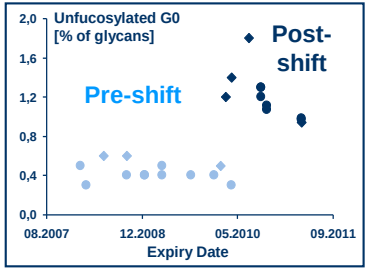


Manufacturing changes

- Manufacturing changes are made frequently
- Differences in attributes can be larger than batch-to-batch variability
- Such changes are stringently controlled by regulators and approved only if they do NOT lead to clinically meaningful differences

Variability of rituximab reference medicine before and after manufacturing change





- Schiestl M, et al. *Nat Biotechnol.* 2011;29:310–2

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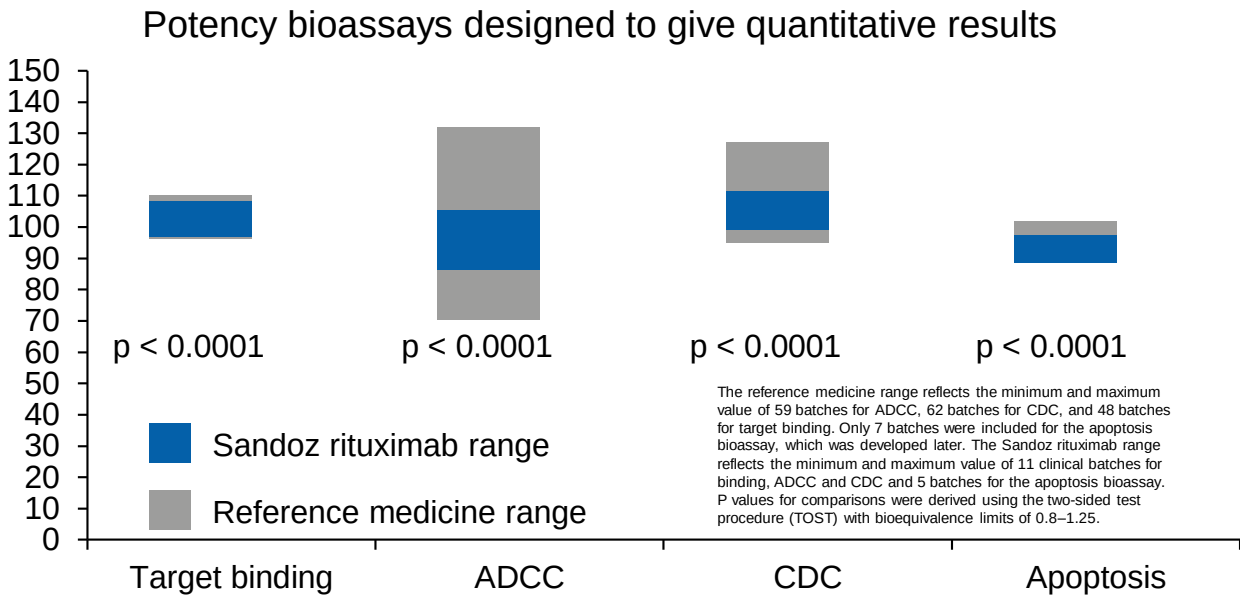
Biological characterization of Sandoz rituximab



Sandoz rituximab is functionally indistinguishable from the reference medicine

- ADCC, antibody-dependent cellular cytotoxicity; CDC, complement-dependent cytotoxicity
- Visser J, et al. *BioDrugs*. 2013;27:495–507.

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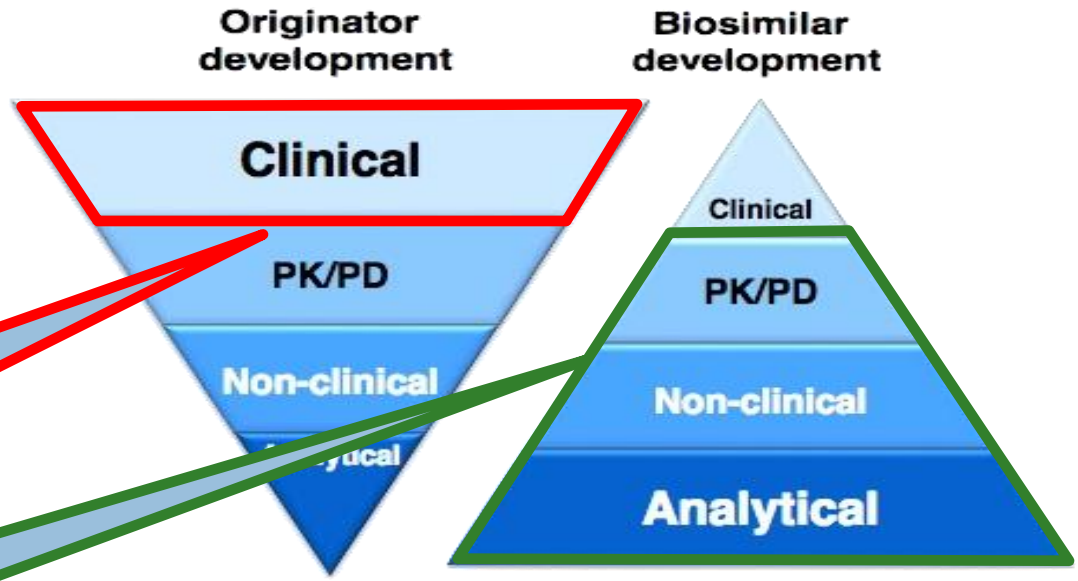
Why do regulators and physicians see biosimilars differently?

Physicians want big clinical trial data

Pharmacists want pharmacological data: analytics, PK, PD & immunogenicity studies

The best way to discover clinical difference for a new drug or indication

The best way to discover that versions of the same drug are not similar



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Key considerations for Phase III trial designs

	Reference medicine	Biosimilar
Patient population	Any	Sensitive and homogeneous
Clinical design	**Superiority versus standard of care**	**Equivalence study vs reference medicine**

Clinical development for EMA-approved rituximab biosimilars

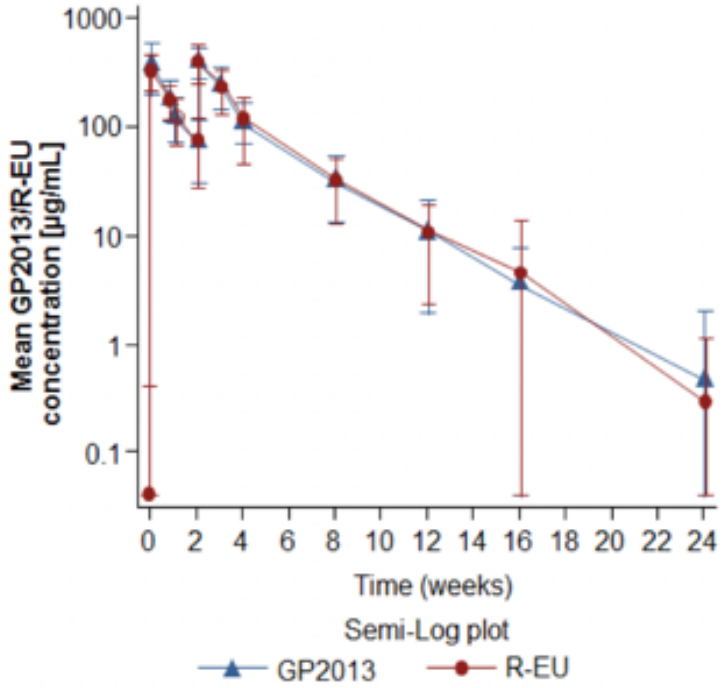
Sandoz rituximab (1054 patients)

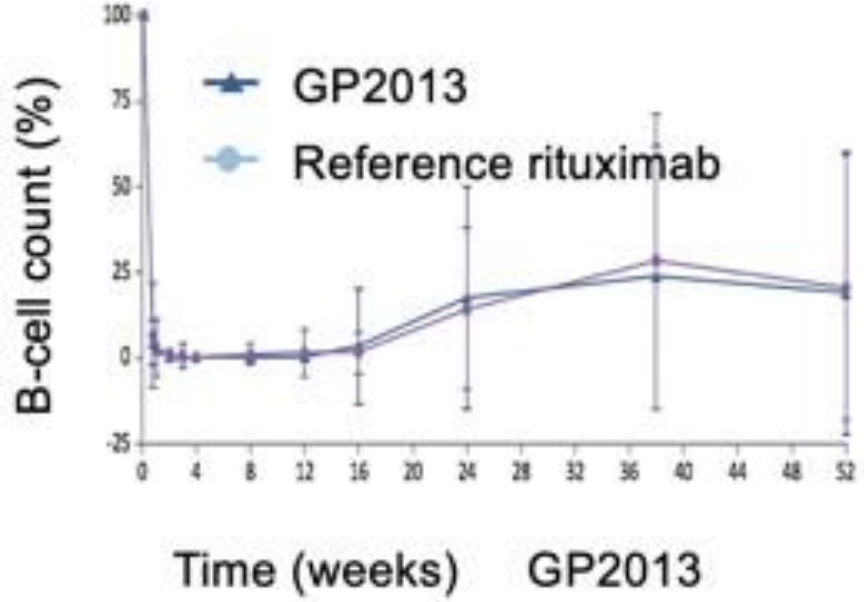
Study	Design	Indication	Primary endpoint	N	Status
JP-trial	Phase I Open-label Single-arm	Indolent LTB NHL	Safety and PK of SDZ-RTX	6	**Completed** NCT01933516
ASSIST-RA	Phase II RCT (1:1:1) Double-blind	RA	PK equivalence between SDZ-RTX and Ref-RTX	312	**Completed** Published[1]
ASSIST-FL	Phase III RCT (1:1) Double-blind	Advanced FL	Therapeutic equivalence between SDZ-RTX and Ref-RTX-EU	629	**Study ongoing** Published[2]
ASSIST-RT	Phase III RCT (1:1) Double-Blind	RA	Safety and immunogenicity	107	**Completed** Published[3]

CT-P10 (982 patients)

Study	Design	Indication	Primary endpoint	N	Status
1.1	Phase I RCT (2:1) Double-blind	RA	PK equivalence between CT-P10 and Ref-RTX	154	**Completed** Published[4,5]
1.3 (1.1 follow-on study)	Phase I Open-label Single-arm	RA	Long-term efficacy and safety of CT-P10	58	**Completed** Published[6]
1.2	Phase I Open-label Single-arm	DLBCL	Initial evidence of CT-P10 safety	N/A	**Terminated** recruitment difficulties[7,8]
3.2	Phase III RCT (1:1:1) Double-blind	RA	PK and therapeutic equivalence between CT-P10 and Ref-RTX	372	**Study ongoing** Published[9]
3.3	Phase I/III RCT (1:1) Double-blind	Advanced FL	PK equivalence and therapeutic non-inferiority between CT-P10 and Ref-RTX-US	140	**Study ongoing** Published[10]
3.4	Phase III RCT (1:1) Double-Blind	LTB FL	Therapeutic equivalence between CT-P10 and Ref-RTX	258	**Study ongoing** Published[10]

Pharmacokinetics and pharmacodynamics of Sandoz rituximab





- Smolen J, et al. *Ann Rheum Dis.* 2017;76:1598–602.

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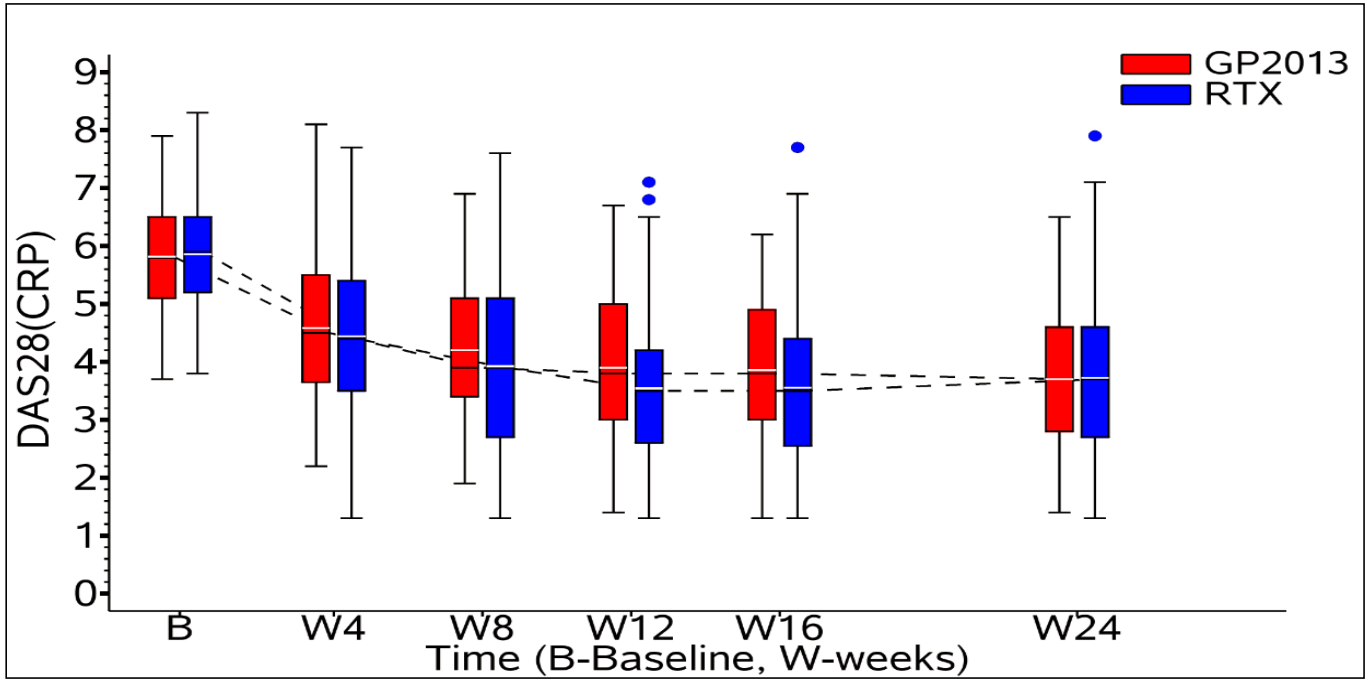
Sandoz rituximab efficacy on Disease Activity Score (DAS)



- Smolen J, et al. *Ann Rheum Dis.* 2017;76:1598–602.

Study rationale in FL

- Studies were **designed to confirm non-inferior clinical effectiveness** of biosimilar as compared to originator rituximab in a **sensitive population**
- **Follicular lymphoma** was chosen as the most appropriate indication as the disease **has a more homogeneous nature** amongst the approved oncology indications of rituximab
- Further, the combination **R-CVP was considered the most sensitive treatment option**, as rituximab had shown the largest additive treatment effect to a chemotherapy backbone treatment in the combination with CVP
- Immunochemotherapy with rituximab **remains the current standard of care** for previously untreated patients , the combination regimen increases the **RR** and prolongs both **PFS** and **OS**

Jurczak W, et al. Lancet Haematol 2017; 4:e350-e361.

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Choosing the disease to study for “confirmation” : Statistical sensitivity

- The indication where the drug makes the greatest statistical impact on a clearly measurable endpoint is the best model for discovering any difference

- A 20% difference in a drug that has a 50% impact is 10%

- A 20% difference in a drug that has a 5% impact is 1%

Pharmacodynamic end-points are likely to be more sensitive than clinical ones

The first indication offers 10x the sensitivity for detecting a difference

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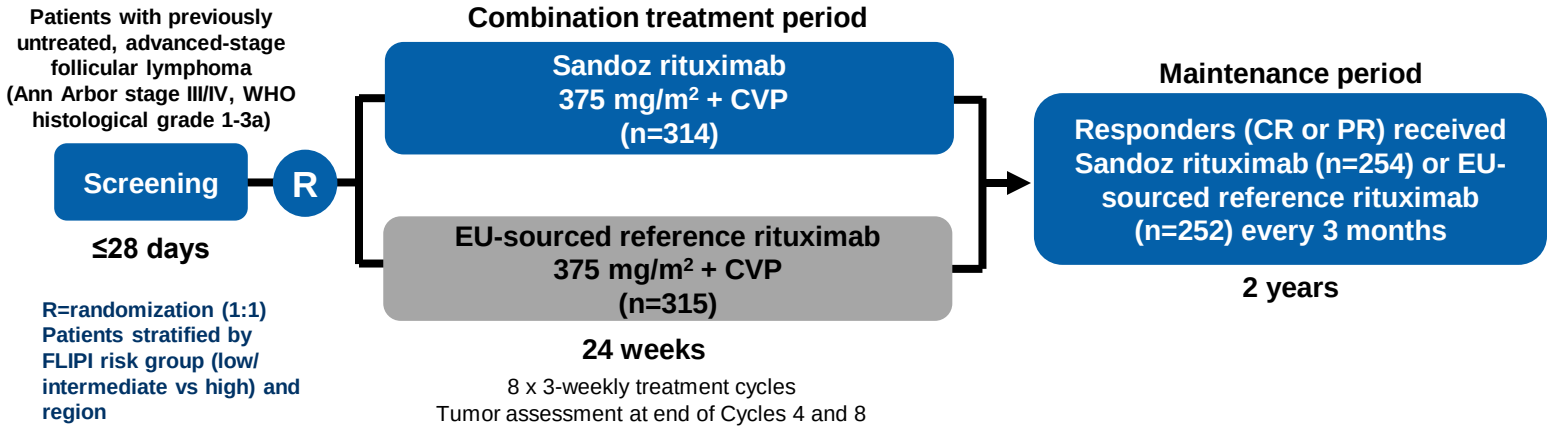
Choosing the disease to study for "confirmation" is a critical step: Statistical sensitivity – example: rituximab and ORR

Indication & pivotal trial result	Chemo + rituximab	Chemo Alone	Absolute Difference	Data Source
1. Follicular NHL induction therapy (R-CVP)	81%	57%	24%	1
2. Diffuse large B-cell lymphoma (R-CHOP)	76%	62%	14%	2
3. Chronic lymphocytic leukaemia (FCR/FR)	86%	72%	14%	3
4. Rheumatoid arthritis (R-MTX)*	51%	18%	33%	4

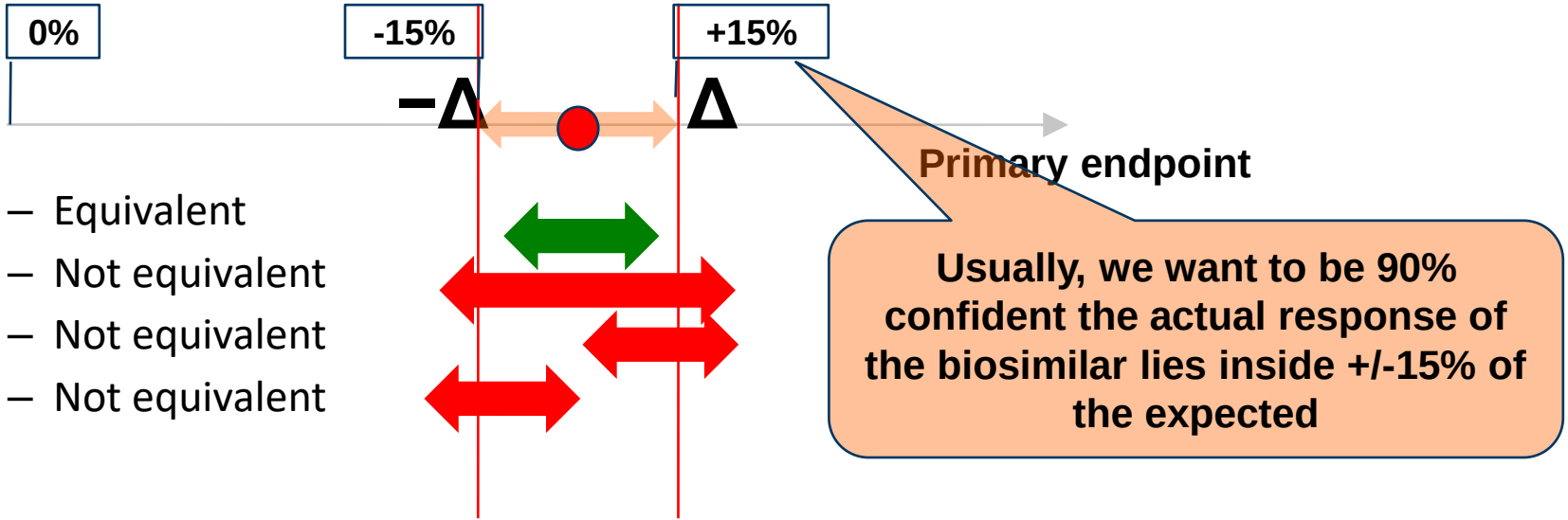
Pharmacodynamic end-points are likely to be more sensitive than clinical ones

ASSIST-FL: randomized, Phase III trial of efficacy, safety and PK of Sandoz rituximab vs EU-sourced reference rituximab



Equivalence trials – show comparability between a biosimilar and its reference drug.

Potential results of a comparability study



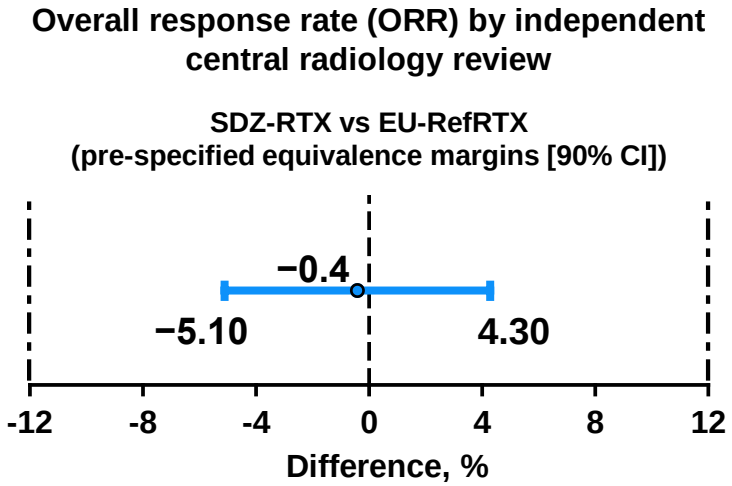
Ref: [1] Isakov L et al. Statistical Primer on Biosimilar Clinical Development. American Journal of Therapeutics 0, 1–8 (2016)

Phase III trial designs for biosimilars vs new biologics in oncology – statistical aspects

Design features	Study for a new biologic	Biosimilar study
Statistical inference	Based on **p-values**	Based on **confidence intervals** (good precision), maintained within pre-defined margins
Analysis approach	**Significance level of 5%** for hypothesis testing Primary analysis on **FAS**	**90% or 95% confidence intervals** Primary analysis on **PPS**
Design type	**Superiority** or **non-inferiority** Powered to show **difference** for primary endpoint (if one exists)	**Equivalence** or **non-inferiority** Powered to show **similarity** for primary endpoint
Error types	Type I: **superiority shown** but **not true** Type II (if study not powered): **superiority not shown** but **actually exists**	Type I: **equivalence shown** but drugs are **not similar** Type II (if study not powered): **difference shown** but drugs are **equivalent**

Primary endpoint was met: equivalence in overall response rate demonstrated

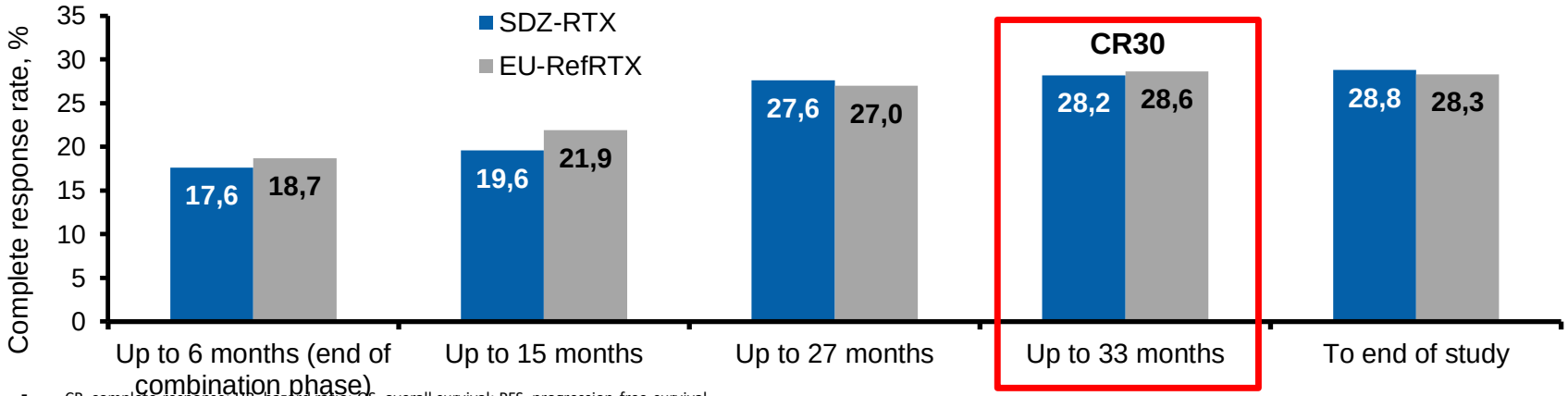
	Response, % (90% CI)	
	Sandoz rituximab (SDZ-RTX) N=311	EU-sourced reference rituximab (EU-RefRTX) N=313
Overall response rate	87.1 (83.59, 90.15)	87.5 (84.04, 90.49)
Complete response	14.8 (11.6, 18.5)	13.4 (10.4, 17.0)
Partial response	72.3 (67.9, 76.5)	74.1 (69.7, 78.2)



- CI, confidence interval, EU-RefRTX, EU-sourced reference rituximab; SDZ-RTX, Sandoz rituximab

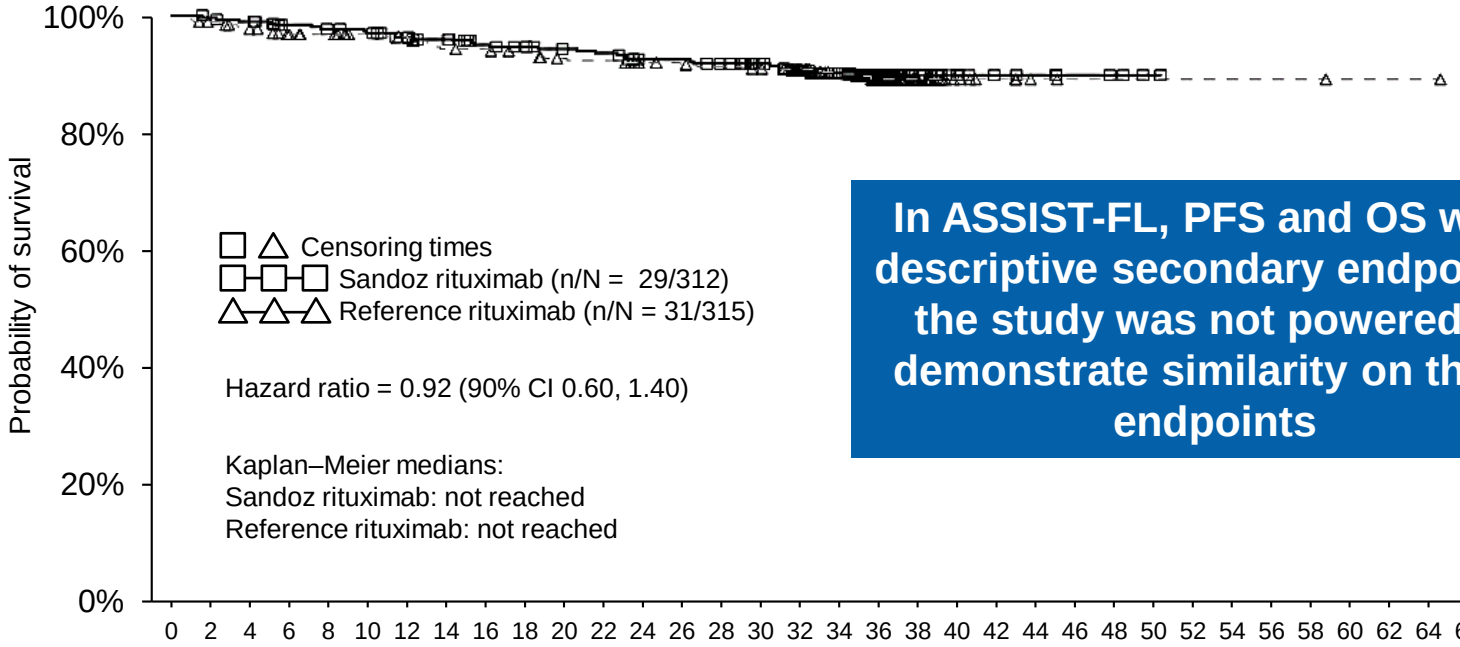
Complete response rates up to month 30 confirm similar efficacy

- Complete response (CR) after 30 months is considered a surrogate for PFS, as correlation between these two outcome measures has been established[1]
  - **CR rates (based on investigator assessment) were similar between treatments at all time points**, including 33 months[2]



- CR, complete response; HR, hazard ratio; OS, overall survival; PFS, progression-free survival.
- Sandoz biosimilar rituximab development code: GP2013.
- 1. Shi Q, et al. *J Clin Oncol*. 2017;35:552–560; 2. Amersdorffer J, et al. Poster 1011P presented at the 2017 Annual Meeting of the European Society for Medical Oncology, Madrid, Spain 8-12 September 2017

Secondary endpoints: OS



In ASSIST-FL, PFS and OS were descriptive secondary endpoints; the study was not powered to demonstrate similarity on these endpoints

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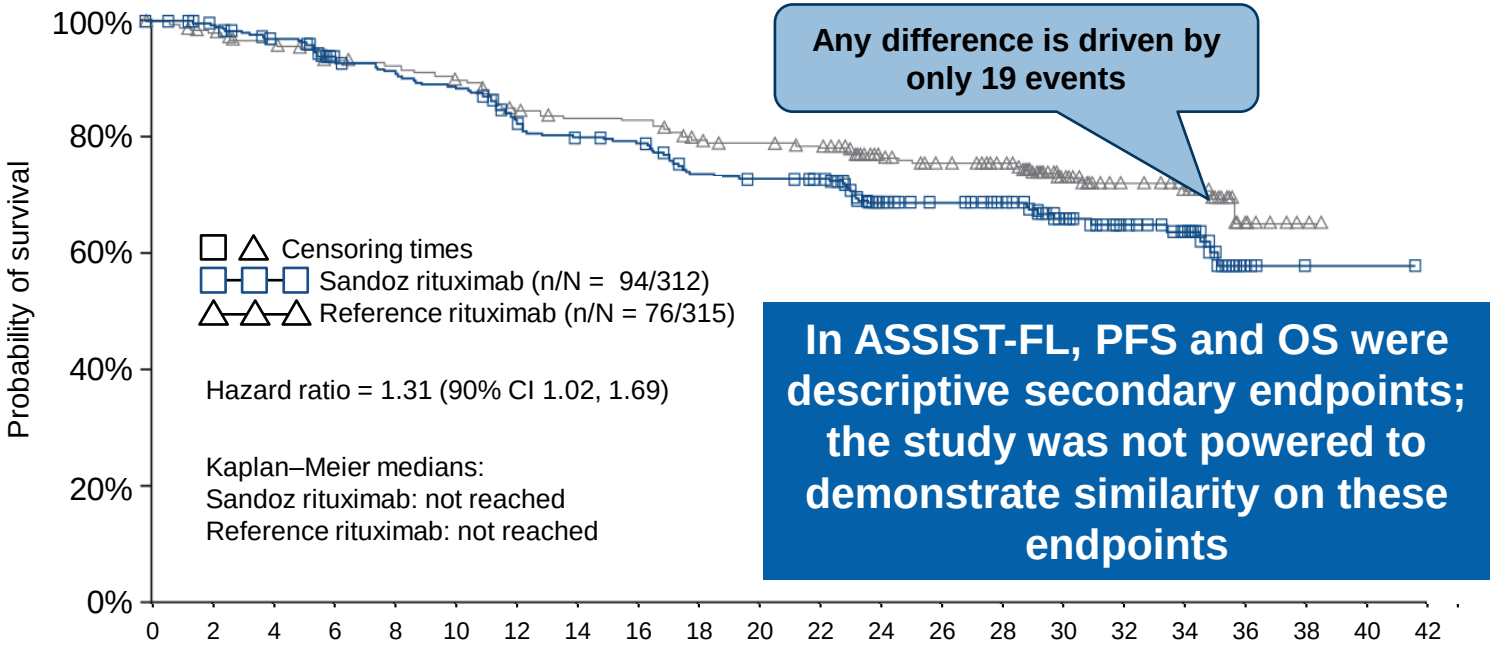
Secondary endpoints: PFS



Additional exploratory analyses performed

Main investigation category	Outcome
Demographics and baseline disease characteristics • At baseline and beginning of maintenance phase	**No imbalances between treatment groups**
PFS subgroup analyses by FL prognostic factors • FLIPI/FLIPI 2 and its components	**No conclusive evidence of subgroup impacting PFS**
CR30: CR rates at month 30 as surrogate for PFS[1]	**Supports similar efficacy, does not support PFS observation**
Change in tumor size (sum of product diameters of index lesions) in individual patents by treatment group • Combination and maintenance phases	**Supports similar efficacy via overlapping tumor shrinkage profiles in responding patients**
OS of patients with early progression (POD24) • Patients who fail to achieve EFS at month 24 have poor subsequent OS[2]	**OS is higher in GP2013 group, opposes PFS observation**
Statistical evaluations of validity of PFS observation • Power of the study to demonstrate equivalence of PFS • Evaluation of significance of the PFS difference • Suitability of Cox proportional hazard model	• Study power to demonstrate PFS equivalence <1%* • 90% CI of the PFS difference cross 0 at all time points – difference not significant • Cox model assumptions violated

- * Assumptions for explorative power assessment presented on slide 15
- 1. Shi Q, et al. *J Clin Oncol*. 2017;35:552–560; 2. Maurer MJ, et al. *Am J Hematol.* 2016;91:1096–1101.

ASSIST-FL: similar safety profiles with Sandoz and reference rituximab

n (%)	Combination phase		Maintenance phase	
	Sandoz rituximab-CVP n=312	Reference rituximab-CVP n=315	Sandoz rituximab n=254	Reference rituximab n=252
Any AE	290 (92.9)	288 (91.4)	183 (72.0)	175 (69.4)
Neutropenia	80 (25.6)	93 (29.5)	30 (11.8)	16 (6.3)
Constipation	70 (22.4)	63 (20.0)	6 (2.4)	8 (3.2)
Nausea	51 (16.3)	42 (13.3)	9 (3.5)	8 (3.2)
Cough	33 (10.6)	37 (11.7)	29 (11.4)	17 (6.7)
Urinary tract infection	–	–	13 (5.1)	23 (9.1)
Grade 3–4 AE	136 (43.6)	144 (45.7)	49 (19.3)	48 (19.0)
Serious AE	71 (22.8)	63 (20.0)	20 (7.9)	18 (7.1)
AE leading to discontinuation	22 (7.1)	22 (7.0)	10 (3.9)	7 (2.8)
Potential infusion-related reaction	228 (73.1)	225 (71.4)	113 (44.5)	123 (48.8)
Deaths	4 (1.3)	7 (2.2)	2 (0.8)	2 (0.8)

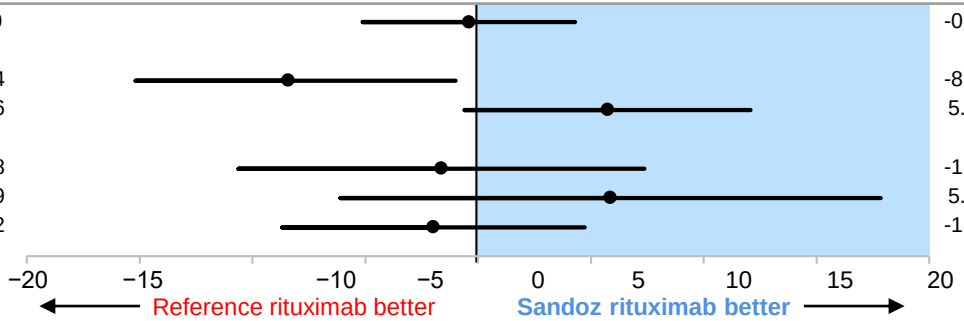
- **Safety profiles of Sandoz biosimilar rituximab and reference rituximab were similar when combined with CVP in the combination phase, or alone in the maintenance phase**
- **Incidences of AEs, SAEs, AEs leading to discontinuations, and deaths were comparable**
- **Most AEs were mild or moderate in severity**

Jurczak W, et al. Lancet Haematol. 2017;4(8):e350-e361; Jurczak W, et al. ESMO, Madrid, Spain 8-12 September 2017: Abstract 994O.

Subgroup analyses by stratification factors (FLIPI score and region)

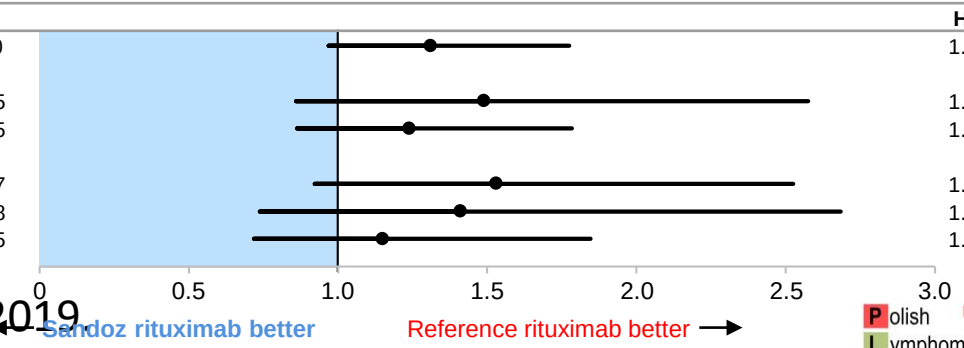
Overall response rate (ORR)

Subgroup	No. of patients	%	Difference	90% CI	
All patients	624	100	-0.40	-5.101	4.298
FLIPI score category					
Score 0–2	271	43.4	-8.41	-15.183	-0.997
Score 3–5	353	56.6	5.74	-0.595	12.068
Geographic region					
Asia-Pacific	180	28.8	-1.63	-10.624	7.363
Latin America	118	18.9	5.87	-6.101	17.835
Europe	326	52.2	-1.98	-8.689	4.728



Progression-free survival (PFS)

Subgroup	No. of patients	%	HR	95% CI	
All patients	627	100	1.31	0.969	1.775
FLIPI score category					
Score 0–2	273	43.5	1.49	0.86	2.575
Score 3–5	354	56.5	1.24	0.863	1.783
Geographic region					
Asia-Pacific	180	28.7	1.53	0.922	2.525
Latin America	118	18.8	1.41	0.738	2.684
Europe	326	52.5	1.15	0.719	1.845



- Sandoz. Data on file, 2019

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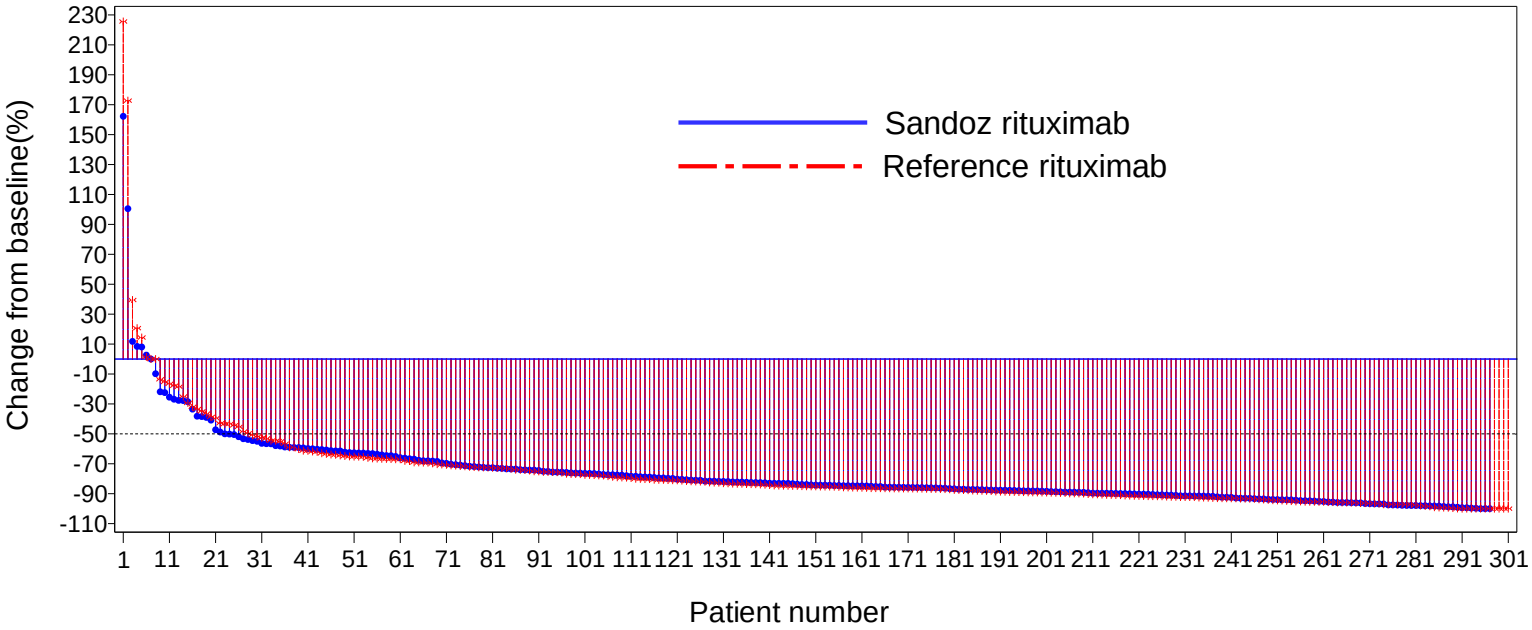
Change in tumor size from baseline to the last assessment in the combination phase



- Sum of product size of the index lesions is included in the analysis
- Sandoz. Data on file, 2019.

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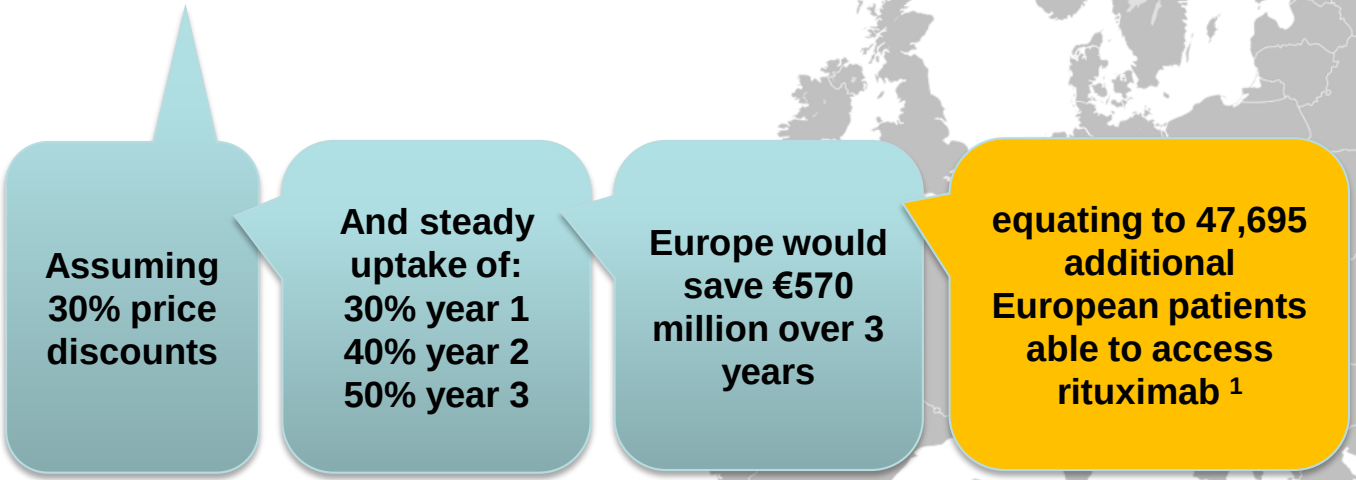
Predicted savings from biosimilars of rituximab in Europe – make it a priority for sustainable Haematology Oncology



Ref: [1] Gulácsi, L., Brodszky, V., Baji, P. et al. The Rituximab Biosimilar CT-P10 in Rheumatology and Cancer: A Budget Impact Analysis in 28 European Countries. Adv Ther (2017) 34: 1128. https://doi.org/10.1007/s12325-017-0522-y [2] Europe Map Image - CCO License. From - https://upload.wikimedia.org/wikipedia/commons/thumb/6/66/Blank_map_of_Europe_cropped.svg/1002px-Blank_map_of_Europe_cropped.svg.png. Accessed May 22 2018

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Predicted savings from biosimilars of rituximab in Poland – make it a priority for sustainable Haematology Oncology

Ponad
80 milionów
PLN rocznie

Ref: [1] Gulácsi, L., Brodszky, V., Baji, P. et al. The Rituximab Biosimilar CT-P10 in Rheumatology and Cancer: A Budget Impact Analysis in 28 European Countries. Adv Ther (2017) 34: 1128. https://doi.org/10.1007/s12325-017-0522-y [2] Europe Map Image - CCO License. From - https://upload.wikimedia.org/wikipedia/commons/thumb/6/66/Blank_map_of_Europe_cropped.svg/1002px-Blank_map_of_Europe_cropped.svg.png. Accessed May 22 2018

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POKONAJ CHŁONIAKA

ZESPÓŁ LECZENIA CHŁONIAKÓW

www.chloniak.org

Co powinno Cię zaniepokoić?

OBJAWY CHŁONIAKA

- Bolesne i tkliwe powiększone węzły chłonne to raczej objaw infekcji niż chłoniaka. Niepokój powinny wzbudzić NIEBOLESNE węzły chłonne oraz pozostałe objawy.

WIĘCEJ

Jeśli pojawiły się u Ciebie objawy.

DIAGNOSTYKA

- Najważniejsze jest postawienie prawidłowego rozpoznania. Mniej istotne jest to, czy rozpoczniemy leczenie od razu, ważne czy będzie one prawidłowo dobrane!

WIĘCEJ

Usłyszałeś diagnozę? Poznaj chorobę!

PODTYPY CHŁONIAKA

- Chłoniaki to zespół chorób o wielkiej różnorodności i dynamice. Przebiegają one w sposób agresywny lub nie wymagający leczenia latami.

WIĘCEJ

Jak walczy się z chłoniakiem?

METODY LECZENIA

- Leczenie chłoniaków jest coraz skuteczniejsze, ostatnie lata przyniosły przełom w postaci rozwoju leków celowanych, które zmieniły standard leczenia.

WIĘCEJ

Kiedy metoda leczenia nie jest refundowana...

BADANIA KLINICZNE

- Większość najnowszych metoda jest w Polsce nierefundowana lub limitowana. Dla pacjenta drogą do ich stosowania w leczeniu są badania kliniczne.

WIĘCEJ

CHŁONIAK TO DIAGNOZA, NIE WYROK

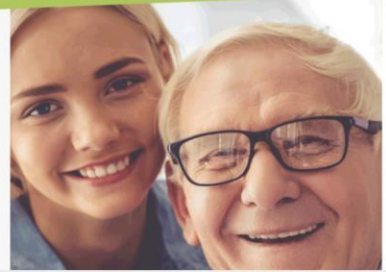
CENTRUM INFORMACJI | JAK KORZYSTAĆ Z TEJ STRONY? | DLACZEGO WERSJA BETA

Witaj w serwisie Pokonaj Chłoniaka!

Najważniejszą informacją dla pacjentów

ze zdiagnozowanym chłoniakiem oraz ich rodzin jest możliwość leczenia tego nowotworu na każdym etapie choroby!

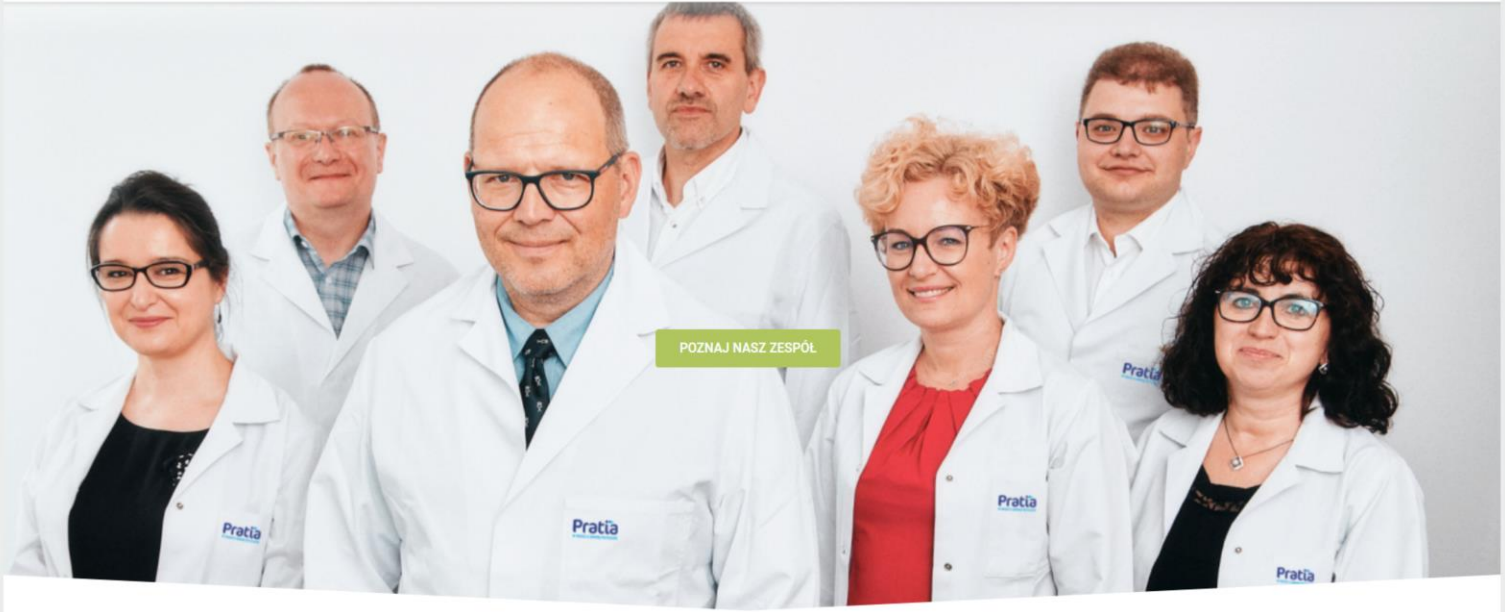
CHŁONIAKI to nowotwory, które mogą być leczone coraz skuteczniej i mniej obciążająco dla pacjenta.



POKONAJ CHŁONIAKA

ZESPÓŁ LECZENIA CHŁONIAKÓW

CHŁONIAKI | BADANIA KLINICZNE | ZESPÓŁ | KONTAKT | 5 KROKÓW w walce z chłoniakiem | STREFA WIEDZY



POKONAJ CHŁONIAKA

ZESPÓŁ LECZENIA CHŁONIAKÓW

W wyniku 25 letniej współpracy doświadczenia w pracy badawczej w ośrodkach krakowskich prof. dr hab. n. med. Wojciech Jurczak zaprosił do współpracy lekarzy z sąsiednich województw, którzy pracować będą wg wspólnych procedur we współpracy z ośrodkiem badań klinicznych w grupie Pratia MCM Kraków, umożliwiając wymianę doświadczeń, wiedzy i konsultacji, a także zwiększanie dostępności do pełnego europejskiego standardu leczenia pacjentów z chłoniakami.

www.chloniak.org

Prof. dr hab. n. med. Wojciech Jurczak
Centrum Onkologii – Instytut
Im. Marii Skłodowskiej - Curie

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