

Galápagos

2019 – preparing for launch

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23 January 2019

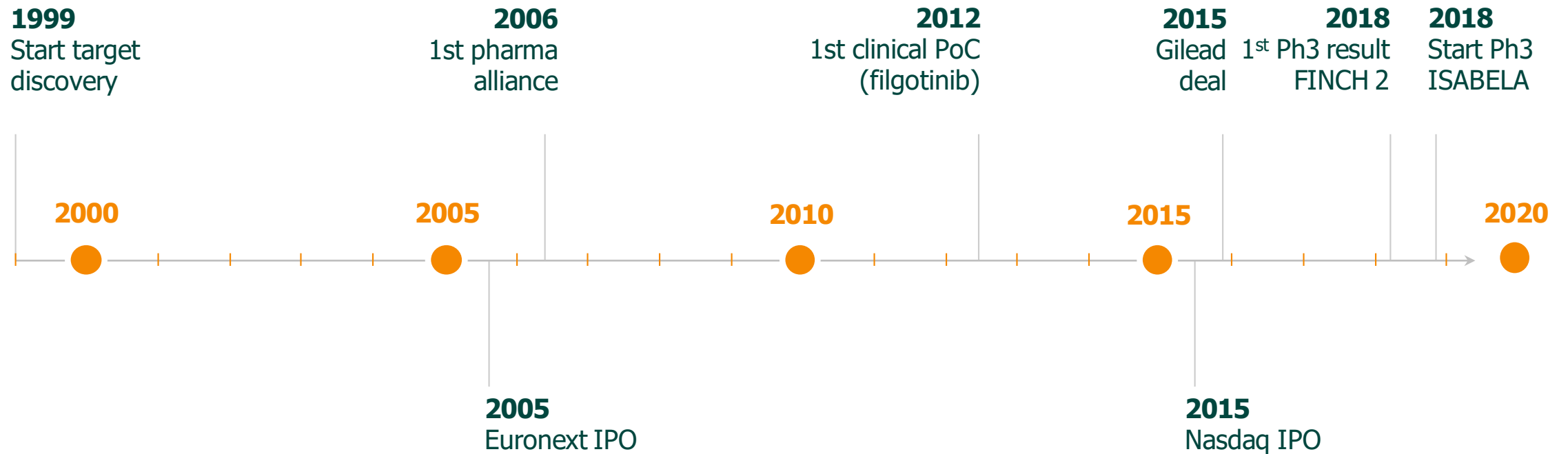


Think big.





Thinking big got us here



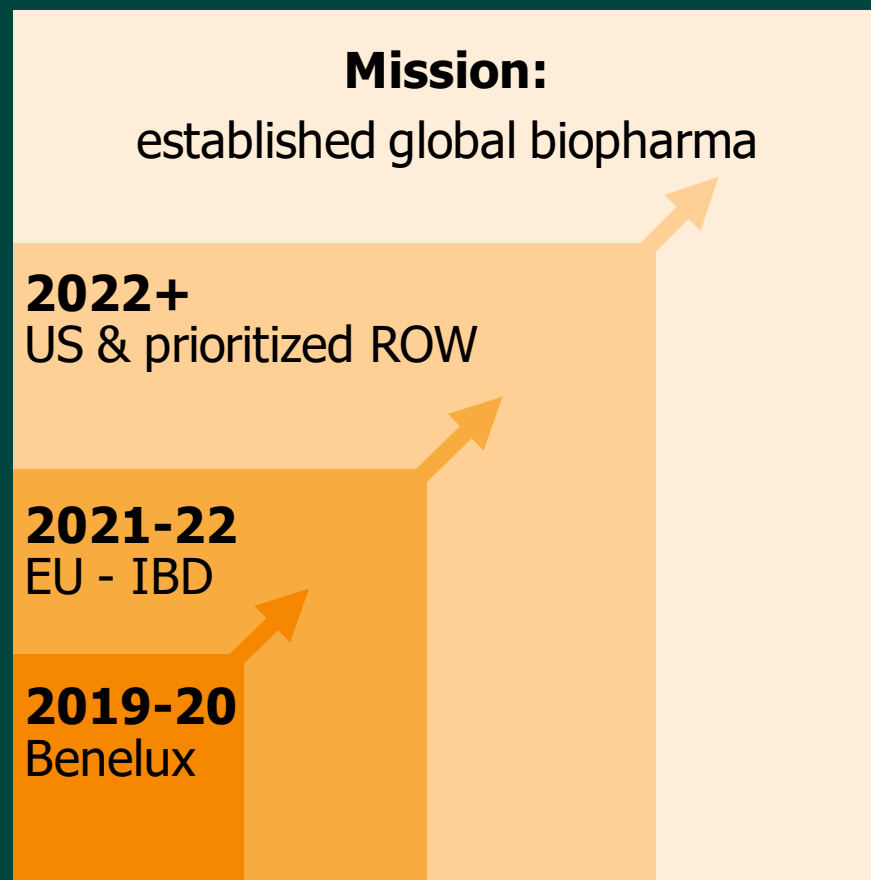


We go step by step on commercial

1690 IPF
global scale, independent launch
collaborations as opportunity

Filgotinib
top EU markets
local Gilead collaboration

Filgotinib
home territory
booking sales





Prolific late stage pipeline

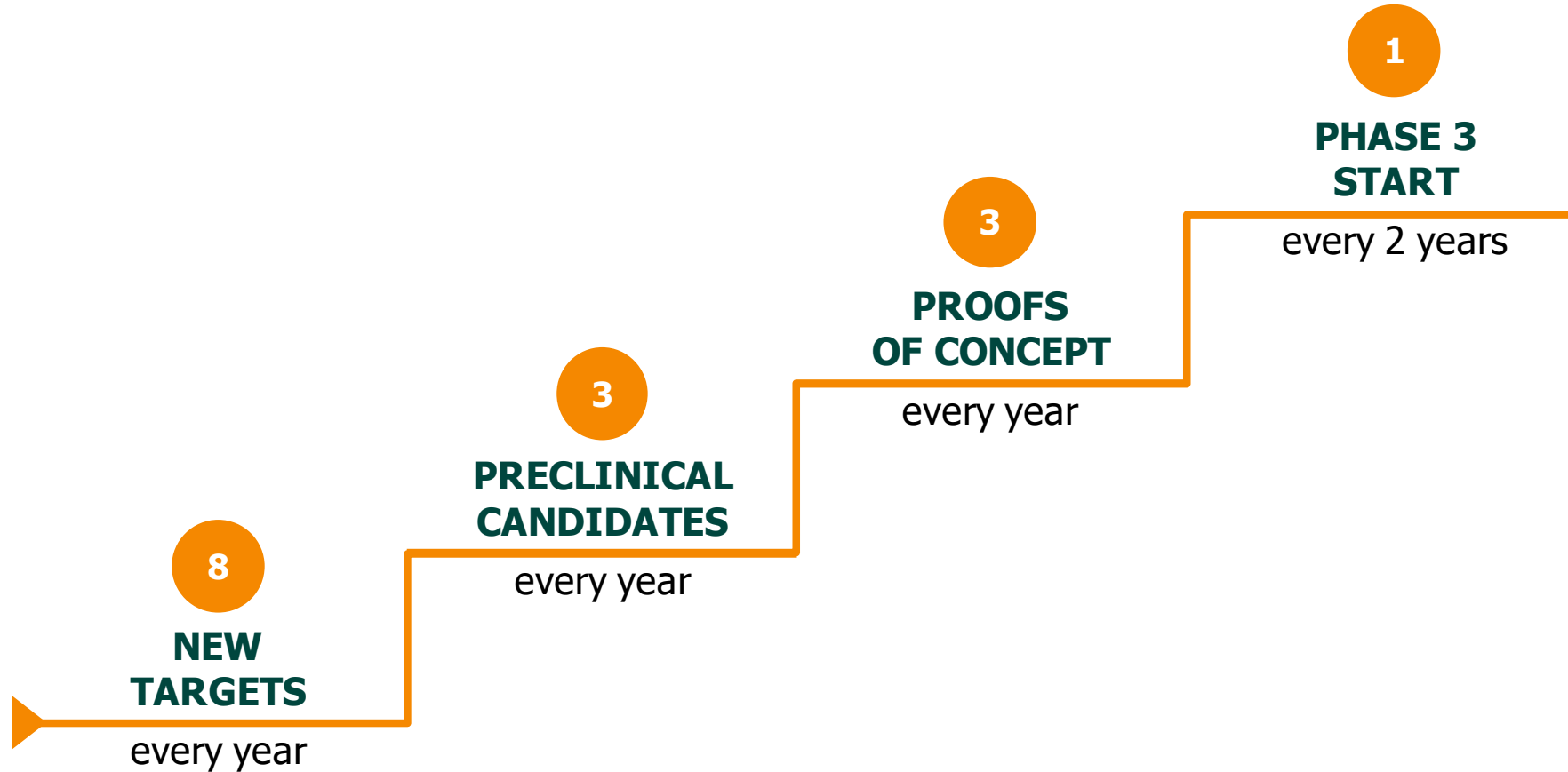
| Area | Preclinical | Phase 1 | Phase 2 | Phase 3 |
|------------------------------|------------------------|---------|---------|---------|
| Filgotinib | 10+ indications | | | |
| IPF/fibrosis | '1690, '1205 | | | |
| OA | '1972 | | | |
| AtD | MOR106 | | | |
| Inflammation Fibrosis | >20 programs | | | |

44 clinical trials planned in 2019



Our R&D engine delivers

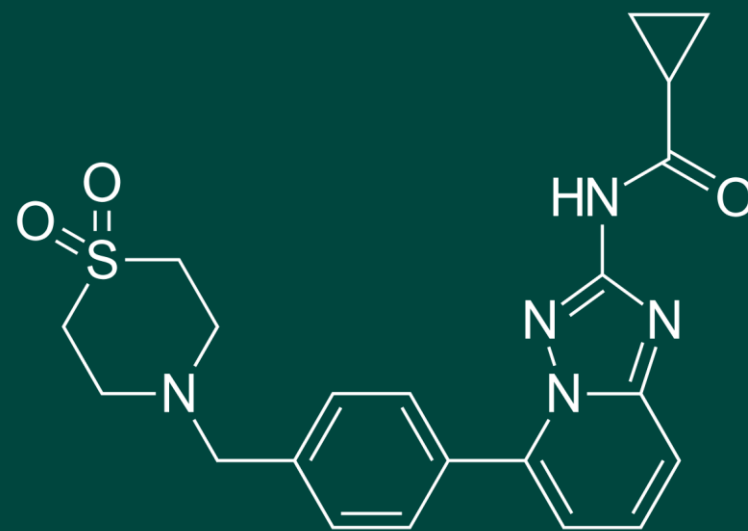
Our goal





Our lead is filgotinib

Evaluated in 11 inflammatory indications





The filgotinib franchise

| Area | Phase 1 | Phase 2 | Phase 3 | Status |
|------------------------|---------|---------|---------|-----------------|
| rheumatoid arthritis | | | | fully recruited |
| Crohn's disease | | | | recruiting |
| ulcerative colitis | | | | recruiting |
| ankylosing spondylitis | | | | study completed |
| psoriatic arthritis | | | | study completed |
| small bowel CD | | | | recruiting |
| fistulizing CD | | | | recruiting |
| Sjögren's | | | | fully recruited |
| cutaneous lupus | | | | recruiting |
| lupus nephropathy | | | | recruiting |
| uveitis | | | | recruiting |

FINCH Phase 3 designs for RA



FINCH 1: MTX - IR

1,759

52 weeks

ACR20
MTX add-on
adalimumab control
radiographic assessment

 **FINCH 2: biologic - IR**

448

24 weeks

ACR20
cDMARD add-on

FINCH 3: MTX naive

1,252

52 weeks

ACR20
monotherapy, +MTX arms
radiographic assessment

FINCH 1 and FINCH 3 topline expected in Q1 '19



Differentiated profile of filgotinib

- Beneficial hemoglobin profile
- No reduction of NK cells & decreased risk of infections
- Reduction of platelets & low incidence of thromboembolic events

JAK1 selectivity makes the difference



Inflammation market \$65B by 2027

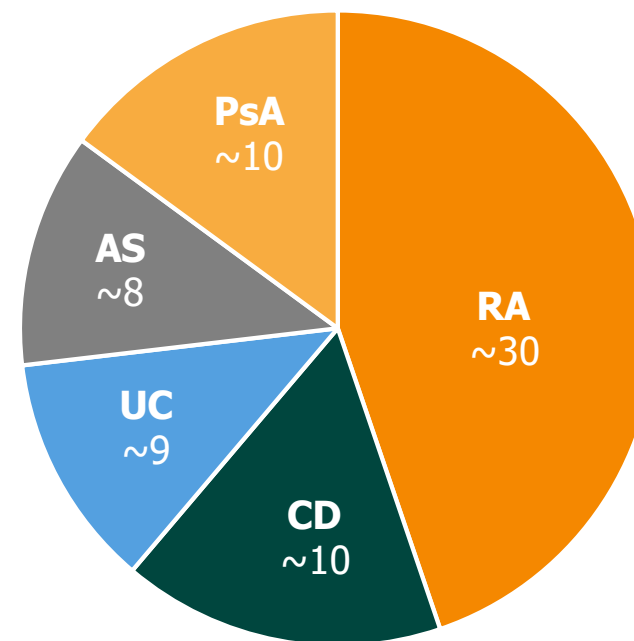
Unmet needs

- Oral
- Rapid response
- Higher, maintained efficacy



Differentiation vs. biologics

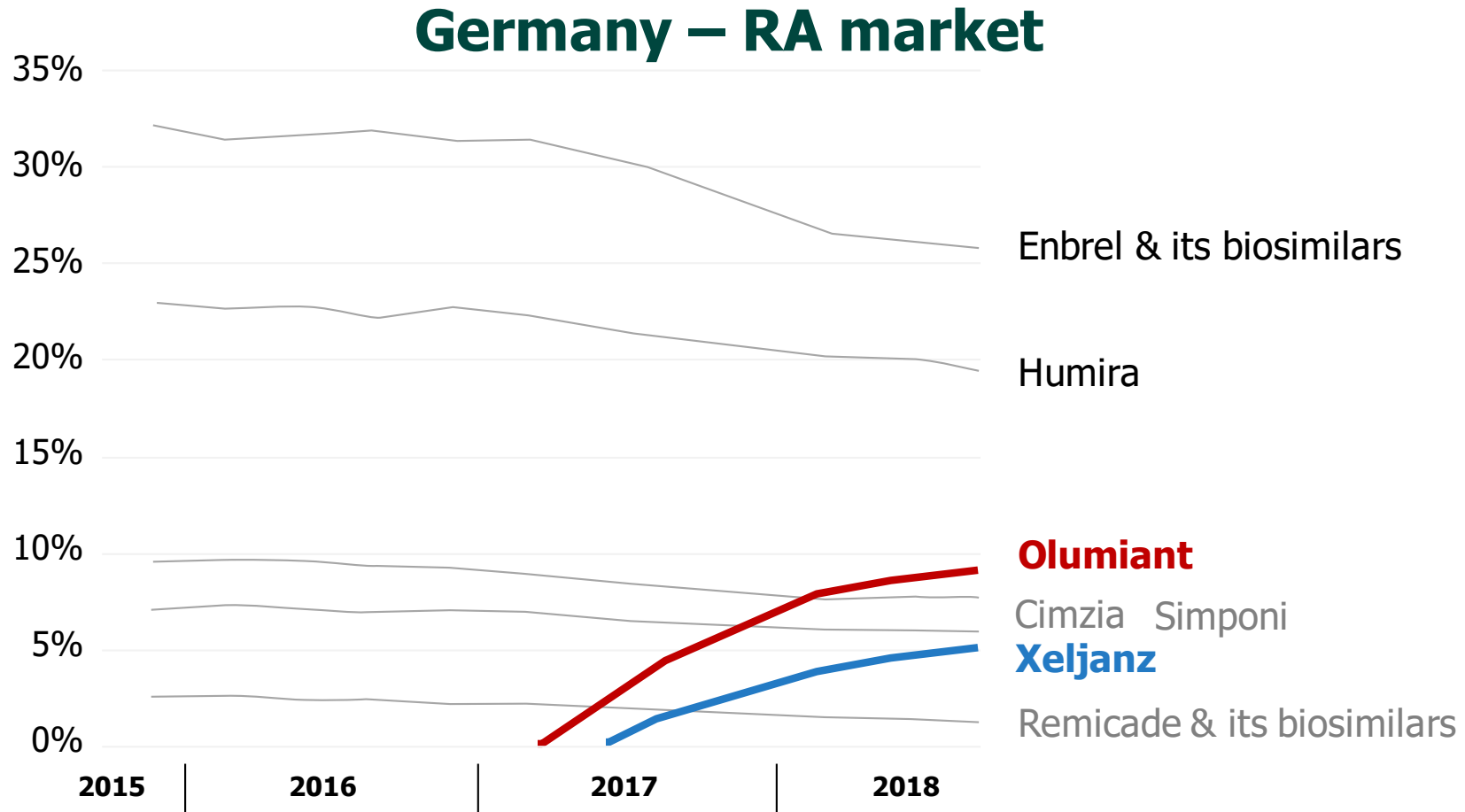
estimated market size, \$B



Source: Goldman Sachs 2017, Leerink 2017, Stifel 2017, Global Data, Galapagos estimates



JAKi's rapidly taking market share



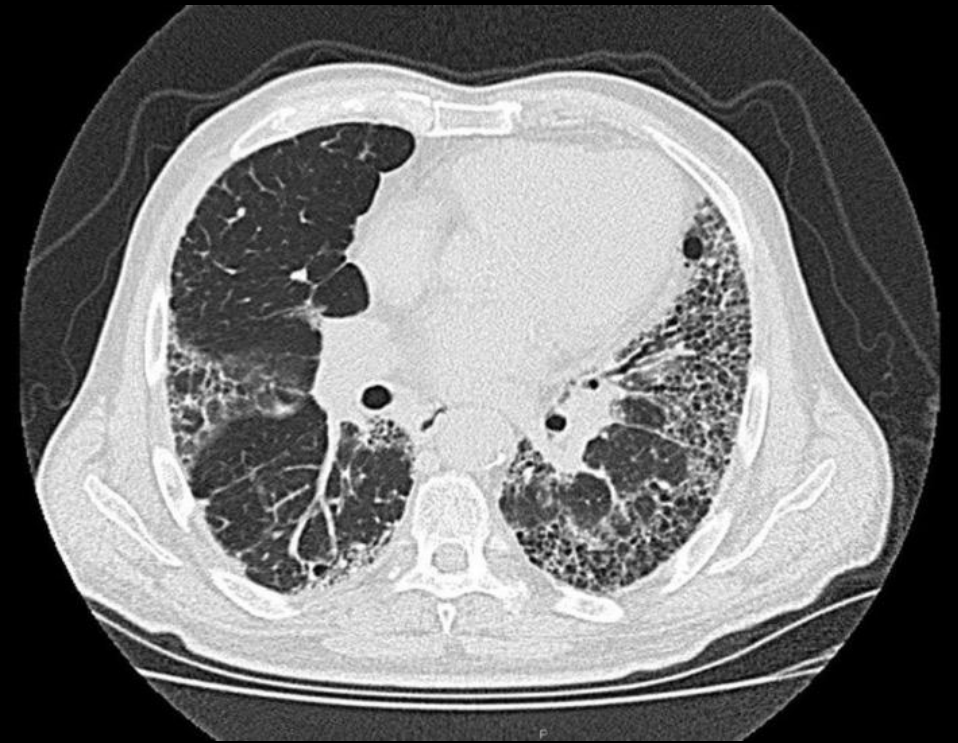
Source: IQVia



IPF

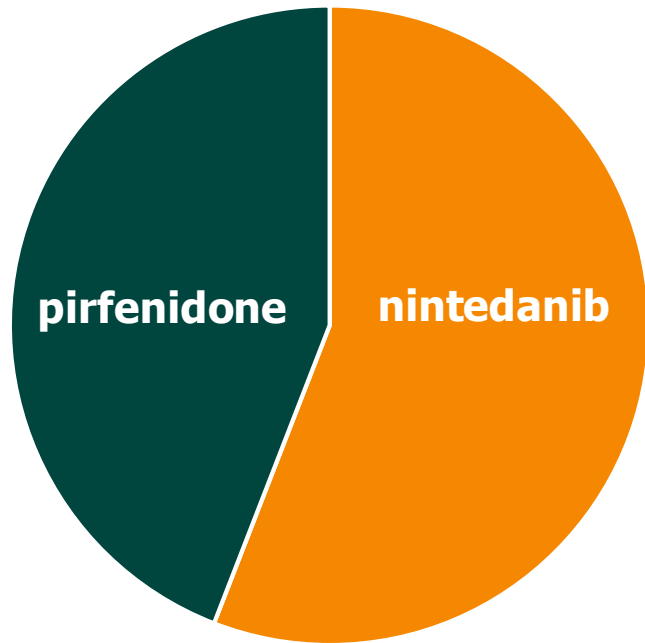
Progressive lung fibrosis leading to death

- 200k cases in US & EU
- 75k new cases every year
- Median survival 2-5 years



IPF - large unmet needs

2017 drug sales \$1.9B



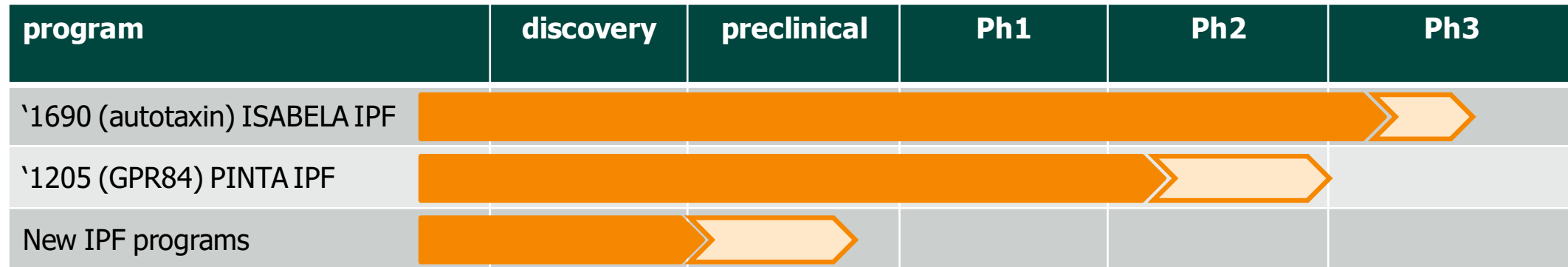
Limitations nintedanib & pirfenidone



- only slow down FVC decline
- poor tolerability
- ~25% annual discontinuations

Sources: Global Data, Maher et al. BMC Pulmonary Medicine (2017) 17:124, sales figures from Roche and Boehringer Ingelheim



We are building an IPF portfolio

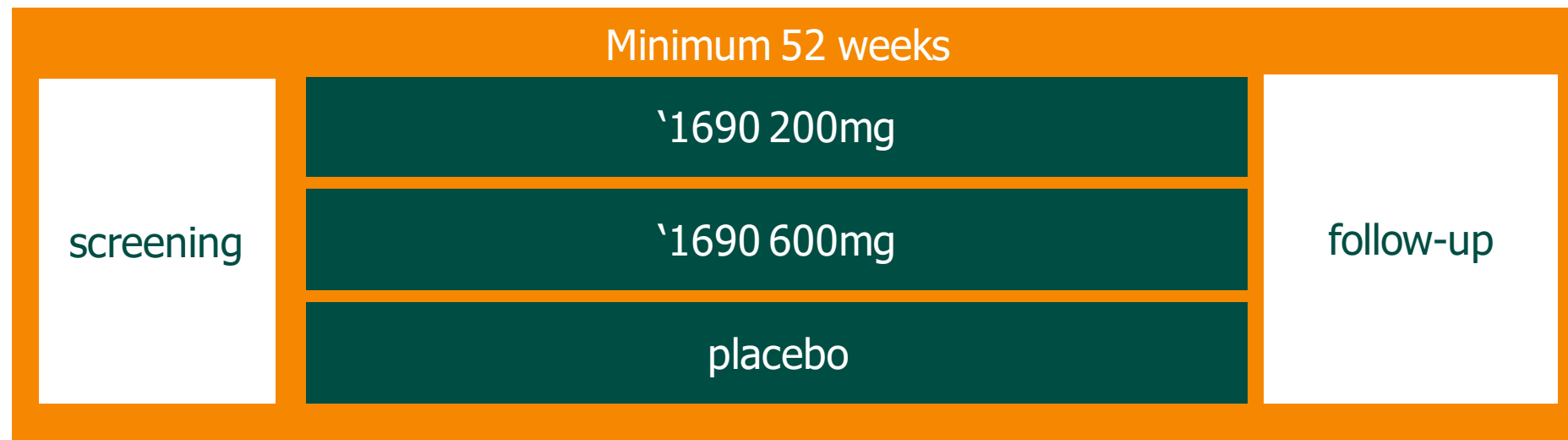


 Status end '18
 Status end '19 (projected)

- Opportunity to combine
- Several programs in discovery



Ph3 program ISABELA



- 1500 patients
- Patients remain on standard of care
- Global program with US & EU component
- Primary endpoint: forced vital capacity (FVC)

Systemic sclerosis - scleroderma

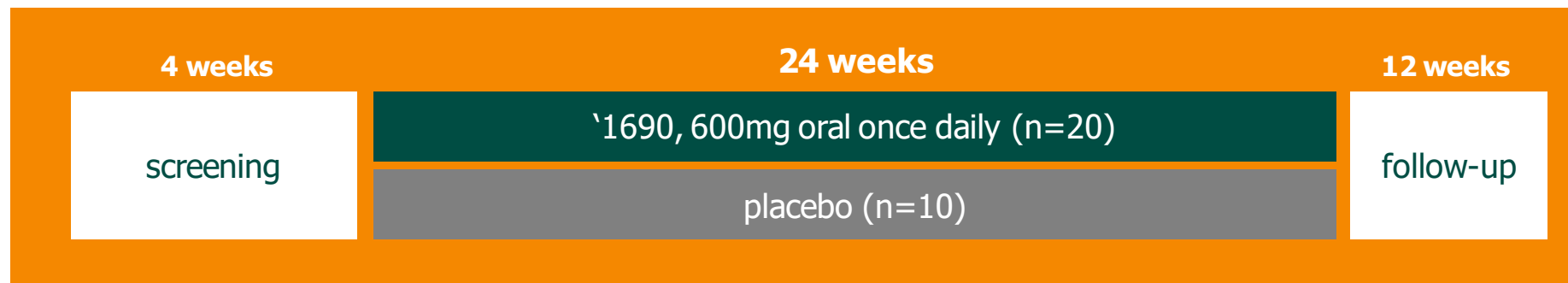
- Multi-organ (“systemic”) fibrosis
- Rare disease: ~95k patients¹
- highest mortality of autoimmune/rheumatic diseases²
- No approved anti-fibrotic drugs³



¹Global Data 2014; ² Nikpour et al Curr Opin Rheumatol. 2014; ³Denton et al Lancet 2017



NOVESA Ph2 in SSc



- 30 patients
- Recruitment in US & 5 EU countries
- Primary endpoint: modified Rodnan Skin Score (mRSS)



'1972

for osteoarthritis (OA)

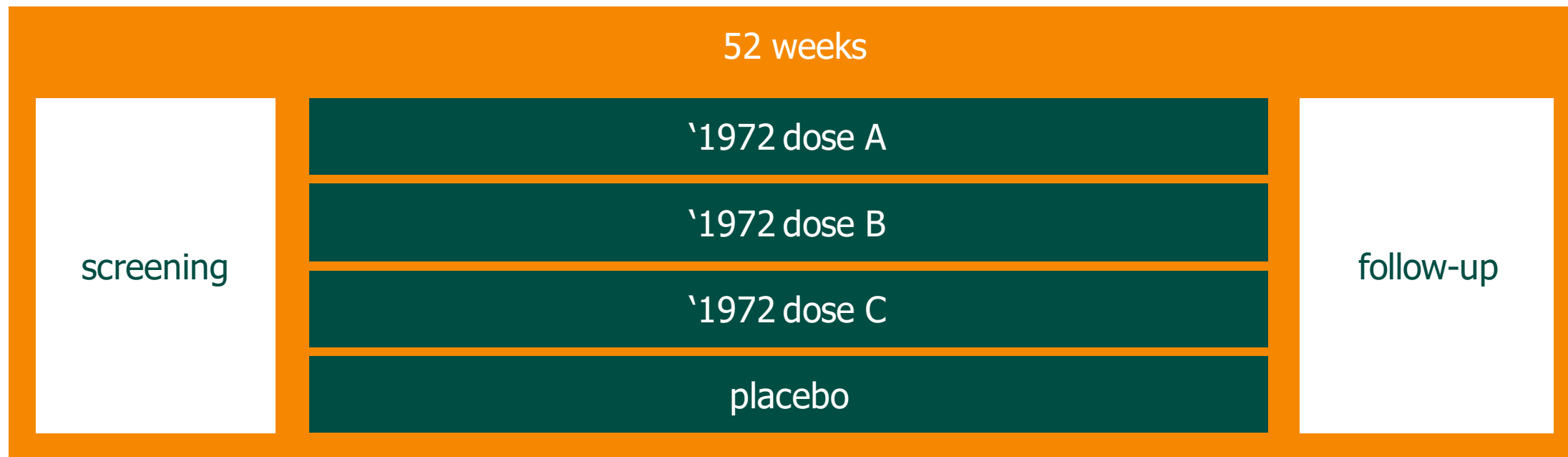
Breakdown of joint cartilage

- 118M patients in US, Europe & Japan
- No disease-modifying drugs





ROCCELLA Ph2 in OA patients ongoing



- 850 patients with knee osteoarthritis, recruited globally
- Primary endpoint: reduction in cartilage

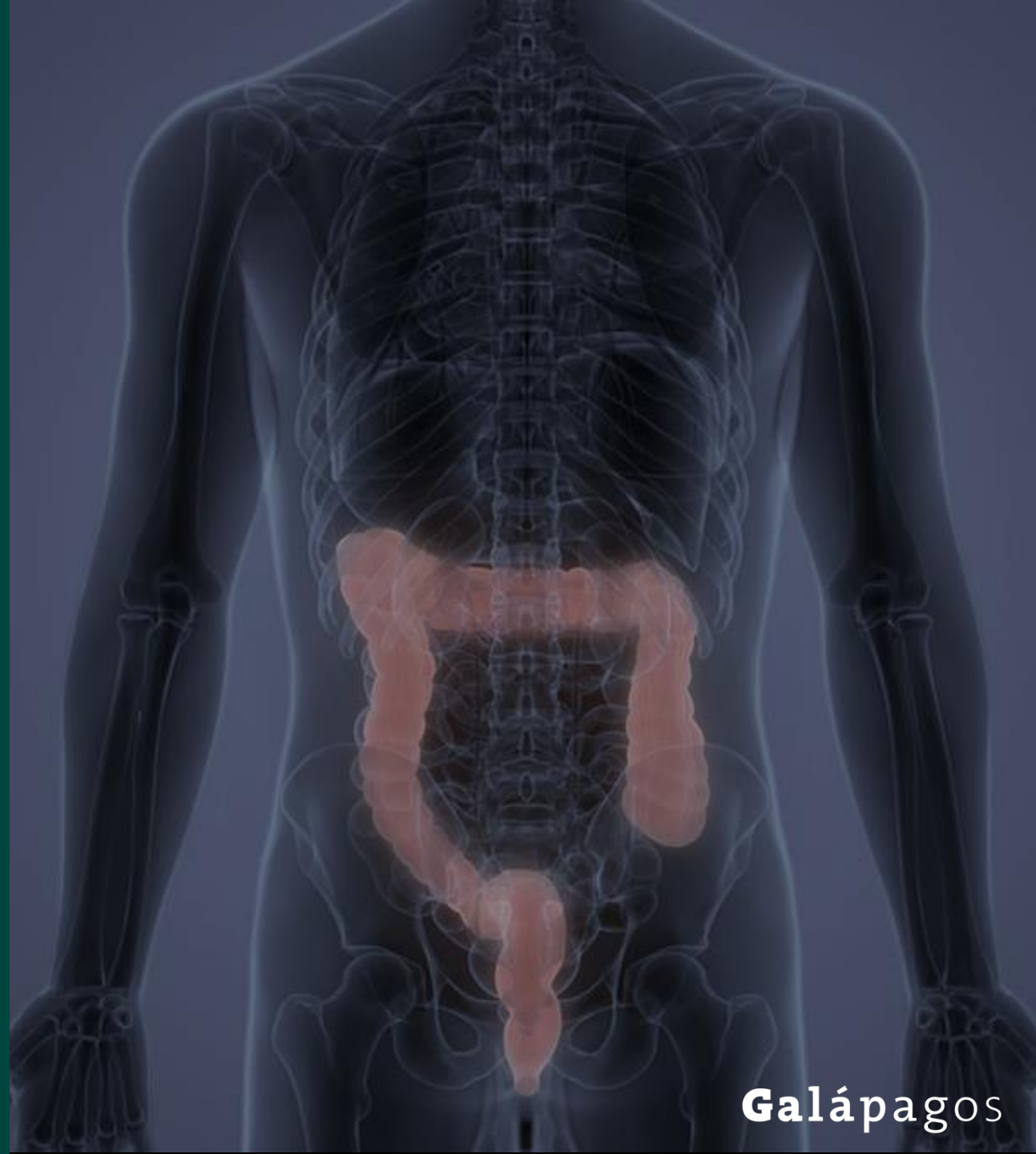
FDA granted fast track status



Toledo

in inflammation

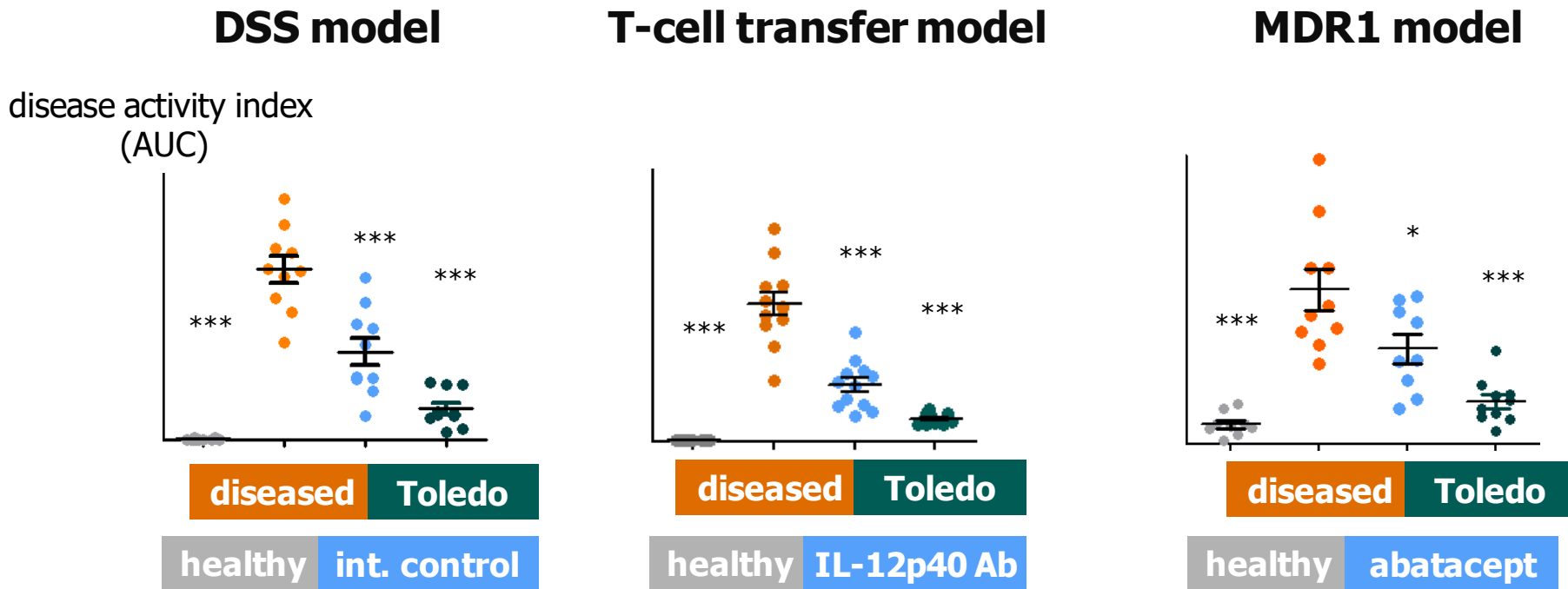
- Novel, undisclosed target
- Dual action
- IBD models show strong activity
- '3312 Ph1 ongoing





Strong activity of Toledo

In 3 IBD models with different mechanisms



*p < 0.05; ***p < 0.001

Our Toledo development strategy

- Develop multiple candidates across different profiles
- Test in broad panel of *in vivo* disease models
- Plan multiple PoC's in patients in parallel to maximize potential

| | | IBD | RA | Pso | PsA | SLE | OA | OP | Fib |
|---------------------|-------|------|------|------|------|------|------|------|------|
| 1 st gen | '3312 | 2019 | 2019 | 2019 | 2019 | 2019 | 2019 | 2019 | 2019 |
| 2 nd gen | '3970 | 2019 | 2019 | 2019 | 2019 | 2019 | 2019 | 2019 | 2019 |
| 3 rd gen | LO | 2019 | 2019 | 2019 | 2019 | 2019 | 2019 | 2019 | |
| 4 th gen | LO | 2019 | | | | | | | |
| 5 th gen | LO | 2019 | | | | | | | |



Expected news in 2019

| | H1 | H2 |
|-------------------------|--|---|
| Filgotinib | FINCH 1 topline wk 24 FINCH 3 topline wk 24 FINCH 2 manuscript publication | Sjögrens PoC topline CLE PoC topline Ph3 PsA start Ph3 AS start Filings for approval in RA |
| Fibrosis | 1st dosing NOVESA SSc '1690 | PINTA recruited <i>ERS</i> <i>ACS (structure)</i> |
| '1972 | <i>OARSI symposium</i> | ROCCELLA recruited |
| MOR106 | GECKO Ph2 start/IND opening Japan study start | IGUANA primary analysis S.C. bridging topline |
| Earlier programs | Start Ph1 '3312 (1 st gen Toledo), '2534, '3121 | Topline '3312, '2534, '3121 Start '3970 Ph1 Start PoC '3312 in IBD |

Boldface = new data



Our challenges

Keep biotech culture

Recruit the best

Stay independent

Deliver

Think big.



Ingezonden vragen – Filgotinib

- MANTA update?
- Samenwerking met Gilead, o.a. voor FDA discussies?
- Filing tijdslijnen - update?
- Analistenforecasts filgotinib, ook buiten RA?
- Kosten van ontwikkeling & commercialisatie filgotinib?

Ingezonden vragen – IPF/Fibrose

- '1690: update recruitment?
- Bekendmaken fertility analysis?
- Impact resultaten fertility analysis op studie?

Ingezonden vragen – Toledo

- Toledo in inflammatie vrij te ontwikkelen gezien Gilead partnership?
- Vertaling *in vitro* modellen naar *in human* anders voor CF dan Toledo?
- Safety?
- Partneringplannen?
- Wanneer belangrijk nieuws te verwachten?
- Naamgevingsthema Toledo trials?

Ingezonden vragen – CF/AbbVie

- Compounds buiten deal gehouden?
- Deal terms – milestones & royalties?
- Take-aways/learnings van moeilijke AbbVie samenwerking?

Ingezonden vragen – OA/'1972

- Partnering in US?
- Nog andere OA compounds met Servier in toekomst?
- Recruitment update?
- Is ROCCELLA een registration trial?

Ingezonden vragen – Strategie

- Status zoektocht naar strategische partner?
- Financing:
 - Nog een kapitaalsverhoging gepland?
 - Waarom korting bij emissies?
- M&A & inlicensing?

Ingezonden vragen – Andere topics

- Totaal aantal GLPG trials in 2019?
- Status metabolics onderzoek (preclinical)?
- Leukste & interessantste meetings op JPM Conference?

Galápagos

