# Making the DARPin® Difference Reality for Patients

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*Presentation of the H1 2018 Results*
*August 30, 2018 – Molecular Partners AG (SIX: MOLN)*

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# Agenda

| | |
|---|---|
| • **Review & Highlights H1 2018** | **Patrick Amstutz, CEO** |
| • **Financial Results H1 2018** | **Andreas Emmenegger, CFO** |
| • **Outlook 2018 & Beyond** | **Patrick Amstutz, CEO** |
| • **Q&A** | **All** |

 

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# Review & Highlights H1 2018

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# Molecular Partners: Who We Are

## Teamwork

- Swiss biotech (SIX: MOLN)
- **120 team members**
- Discovery to Phase 2 (POC)
- Science & patients first

## DARPin® Therapies

- **Abicipar** in Phase 3 (ophtha)
- MP0250 in Phase 2 (onc)
- MP0274 in Phase 1 (onc)
- Broad preclin. I/O portfolio

## Partnerships

- Alliance with Allergan
- **Agreement with AstraZeneca**
- **Cash CHF 122m (H1 2018)**
- Financed well beyond key value inflection points

## DARPin® Engine

- DARPin® Difference: test novel therapeutic design
- Proof of DARPin® candidates in eye and systemically
- Fast and cost effective drug discovery engine

 

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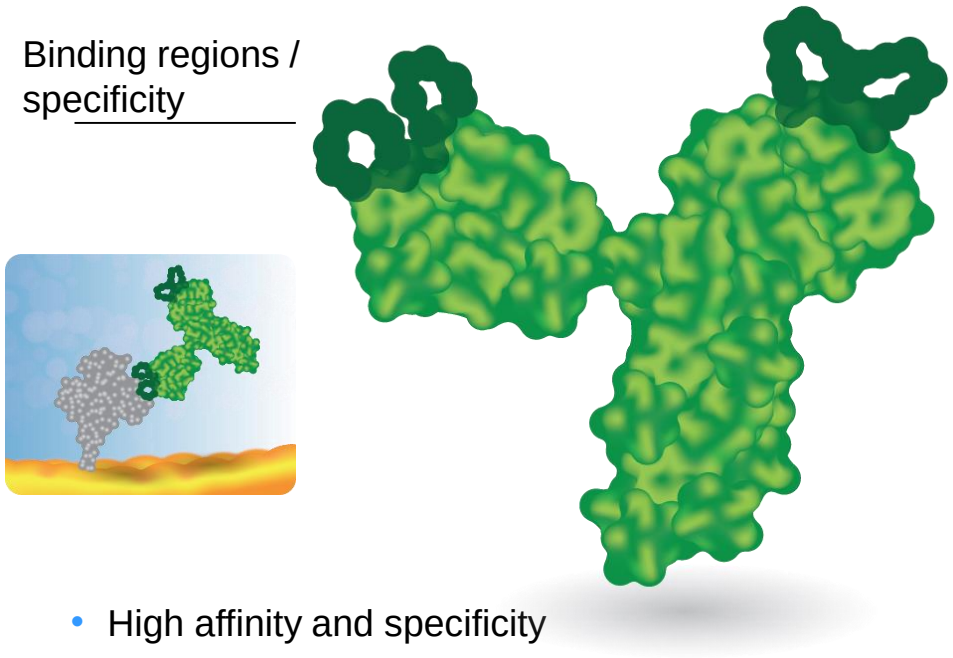
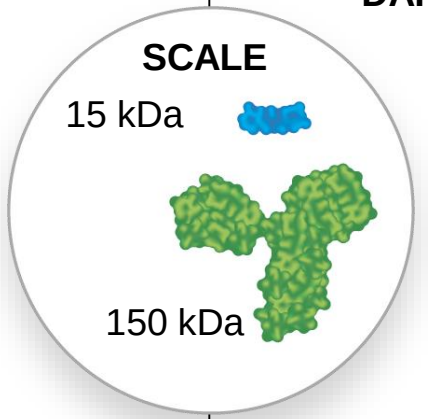
# DARPin® Proteins: Beyond Target Space of Antibodies

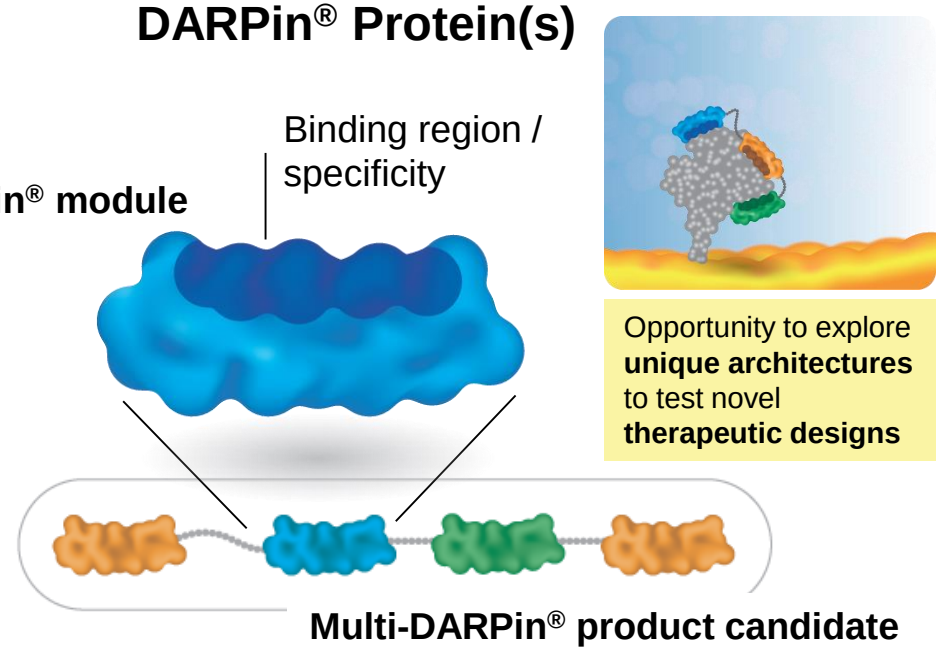
## MONOCLONAL ANTIBODIES




- High affinity and specificity
- Large size: 150 kDa
- Complex architecture: 4 proteins with 12 domains
- Target binding via flexible surface loops (CDRs)
- Long half-life




## DARPin® Protein(s)




- High affinity and specificity
- Small size: 15 kDa (1/10 of monoclonal antibody)
- Simple architecture: 1 protein with 1 domain
- Target binding via rigid surface structure
- Tunable half-life

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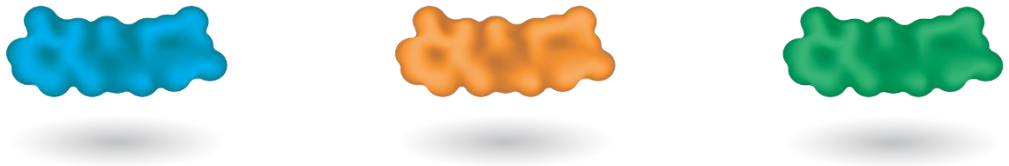
# Modular Approach to Customized Drug Candidates

## Building blocks

DARPin® modules

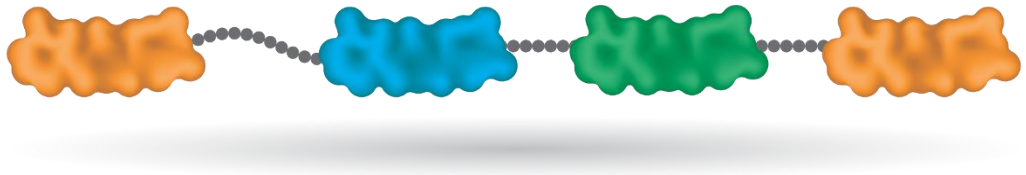


Peptide linkers: Short, long, flexible, rigid

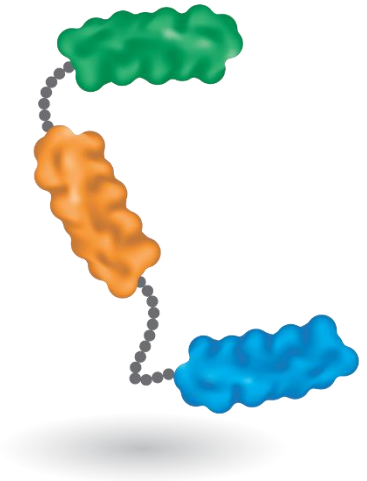
Non-DARPin® element (chemical, toxin or other proteins)

## Candidates

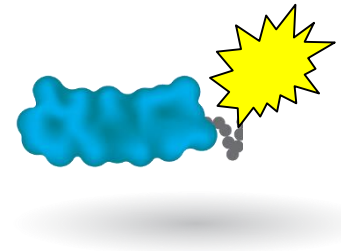
Multi-DARPin® product candidate (e.g. MP0250, MP0274)



High flexibility permits binding with complex geometries



DARPin® module conjugated to non-DARPin® element



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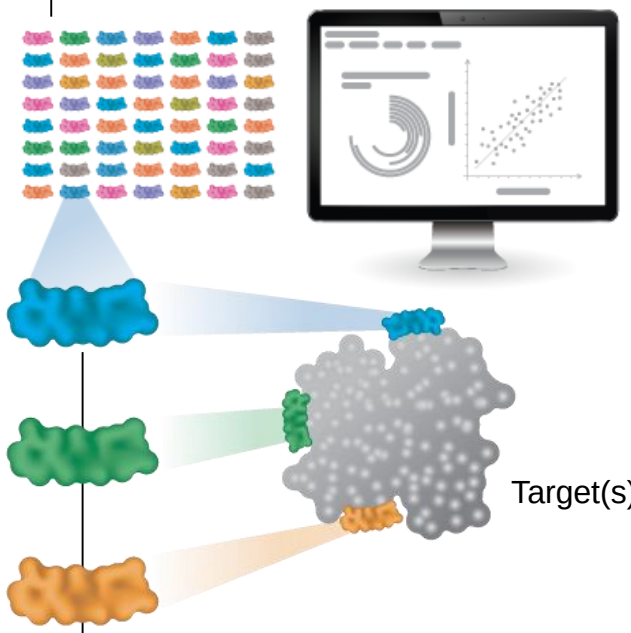
# DARPin® Engine: Rapid Screening and Discovery, Flexible Design, Tailored to Therapeutic Need

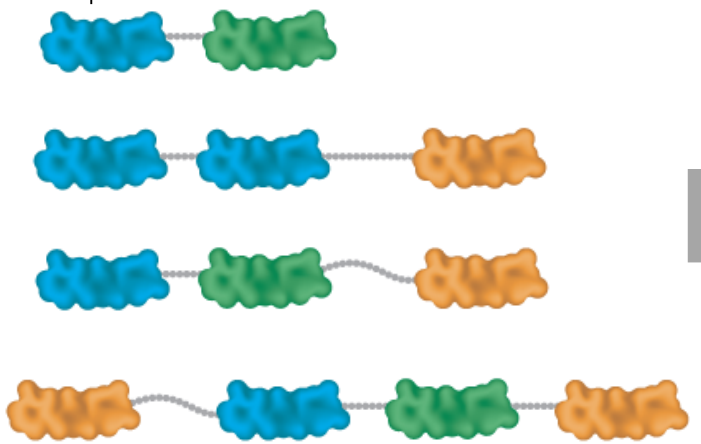
## DARPin® module selection

Library of over 1 trillion DARPin® proteins (modules)



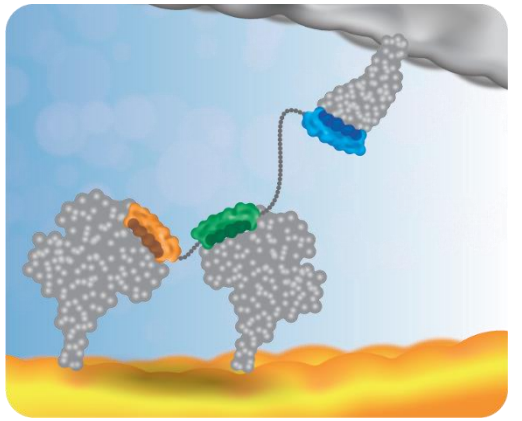

## Screening multi-DARPin® space of up to 10,000 functional combinations

Combinations of up to 6+ DARPin® modules, linkers



Multi-DARPin® product candidates

## Identifying novel therapeutic designs



Multi-DARPin® product candidate

# R&D Highlights 2018 to Date - Oncology

- **MP0250 in MM -** Promising initial data from MP0250 combination with Velcade® in ongoing phase 2 study:
  - Five of eight (5/8) evaluable patients achieved objective response
  - Median time of treatment for responding patients of 22.5 weeks

- **MP0250 in EGFR mut NSCLC -** Ongoing phase 2 study in combination with Tagrisso®:
  - Supply agreement with AstraZeneca for free supply of Tagrisso®
  - Enrollment and patient dosing ongoing

- **MP0274 in HER2-positive solid tumors -** Ongoing phase 1 study:
  - Protocol amended to allow enrollment of more patients at lower doses
  - Enrollment and patient dosing ongoing

- **Immuno-oncology and DARPin® I/O toolbox:**
  - Preclinical data presented at AACR 2018
  - **MP0310:** FAPx4-1BB multi-DARPin® product candidate, first candidate out of the DARPin I/O toolbox

# R&D Highlights 2018 to date - Ophthalmology

- **Abicipar:**
  - July 2018: Allergan presented positive phase 3 topline data on abicipar, demonstrating non-inferiority in 12-week fixed dosing regimen with <50% injections vs. Lucentis®
  - Abicipar has potential to be the first and only 12-week anti-VEGF drug for nAMD and DME
  - Abicipar inflammation rate was 15% and optimized formulation to reduce inflammation is being tested (MAPLE trial)
  - Allergan plans FDA filing in H1 2019 and launch in 2020 in nAMD
  - Allergan expects to start Phase 3 studies in DME (diabetic macular edema) in 2019

- **Discovery Alliance:**
  - Allergan exercised options for development of two additional DARPin® product candidates
  - All options from the Discovery Alliance have been exercised

# Team Highlights 2018 to date

- Bill Burns, former CEO of Roche Pharmaceuticals, elected as Chairman of the Board of Directors at 2018 AGM
- Pamela A. Trail, Ph.D., appointed as Chief Scientific Officer
- Michael T. Stumpp, Ph.D., assumes Role of Chief Operating Officer
- Talent base with 112 FTE (+8% y-o-y), reflecting further build-out of oncology expertise

# Financial Highlights H1 2018

- Ongoing strong financial position, debt-free:
  - CHF 122.4 million in cash as of June 30, 2018 (-CHF 34.5 million or -22% y-o-y)
- Net cash used in operating activities of CHF 19.4 million in H1 2018 (-5% y-o-y), reflecting:
  - Ongoing scale-up of R&D to accelerate pipeline growth
  - Progress of proprietary oncology programs; reduced manufacturing costs for MP0250
  - Ongoing build-out and growth of organization
- Operating loss of CHF 12.7 million and net loss of CHF 11.7 million
- Forecasted cash runway into 2020, excluding any projected proceeds from abicipar

# Highlights: Pipeline & DARPin® Product Candidates

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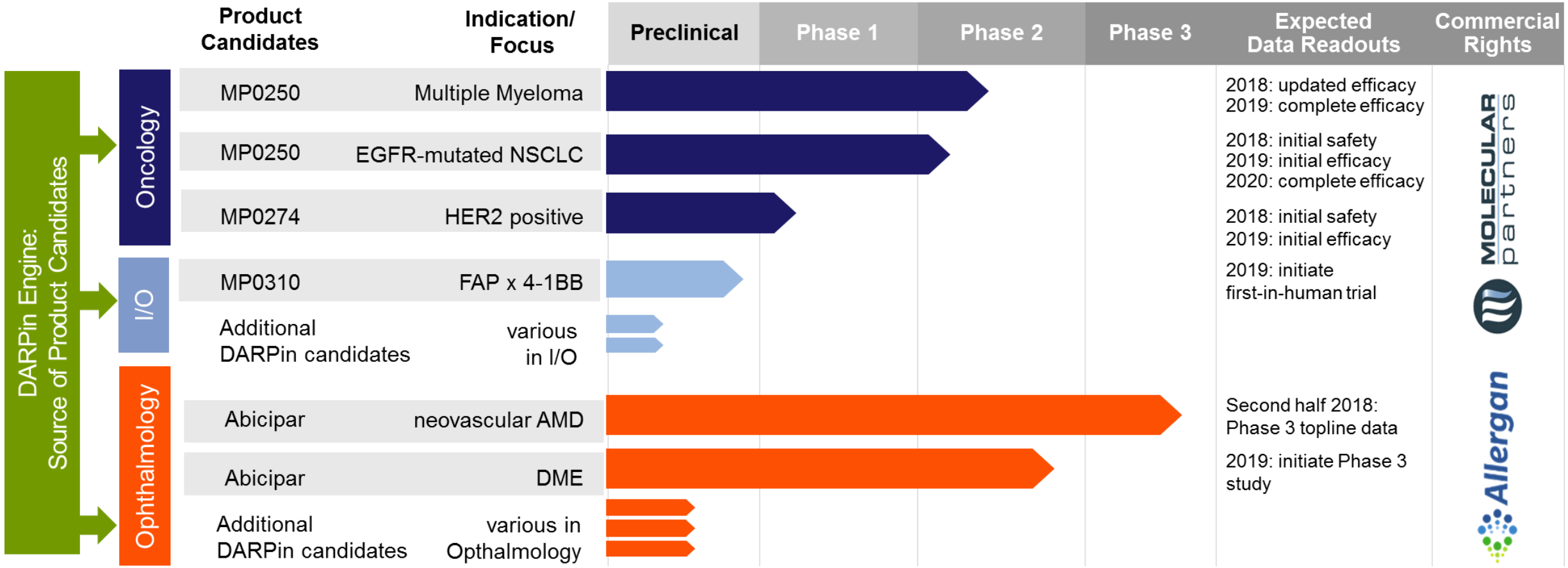
# Pipeline: A Balanced and Robust Portfolio




AMD: age-related macular degeneration; DME: diabetic macular edema; NSCLC: non-small cell lung cancer

# Clincial Stage Oncology:

# MP0250 & MP0274

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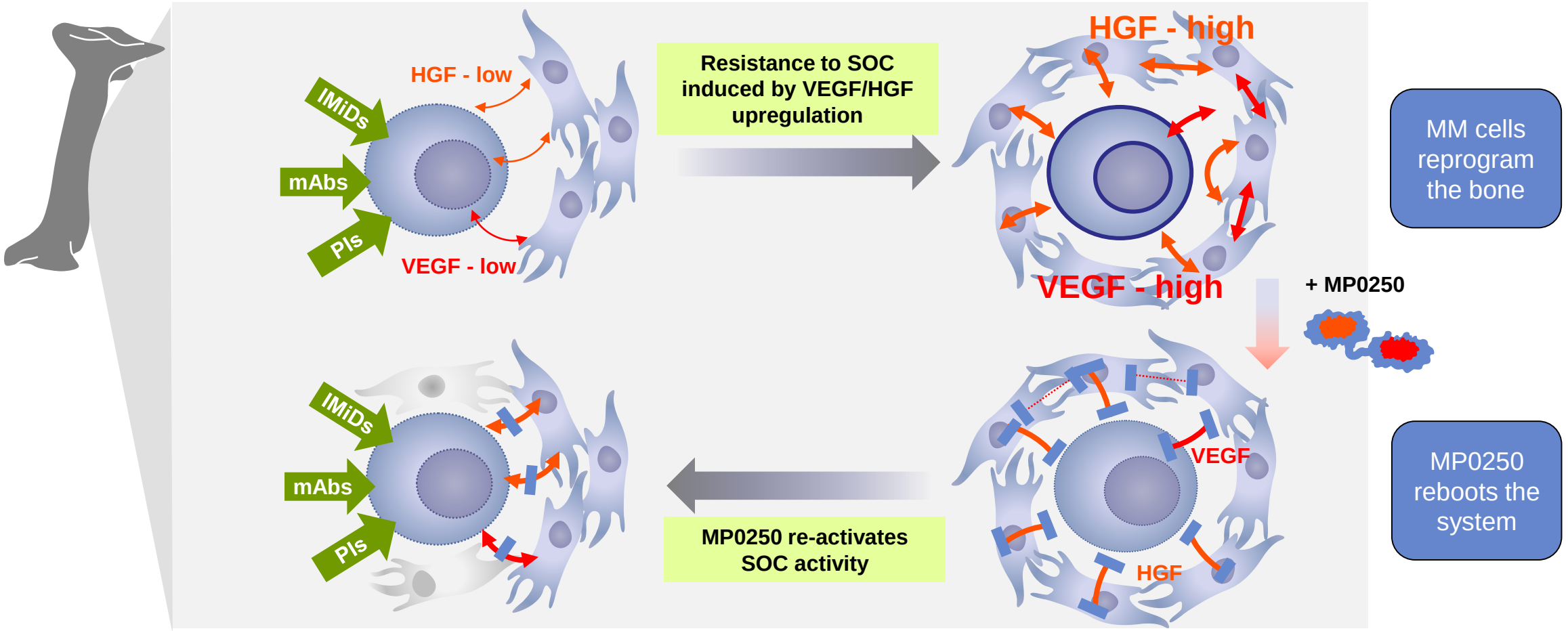
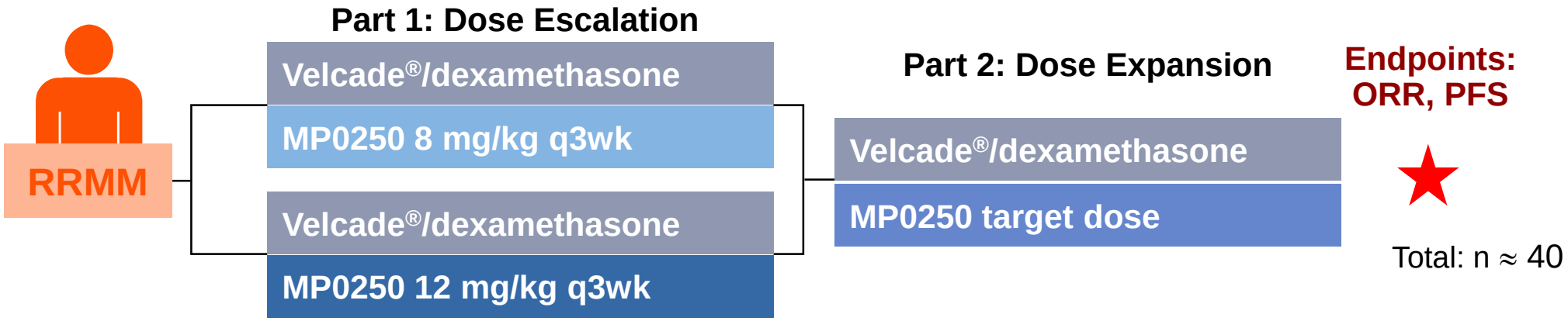
# MP0250 Unique Approach in MM – Break Resistance & Restore Sensitivity



# MP0250 Phase 2 Study in MM

MP0250



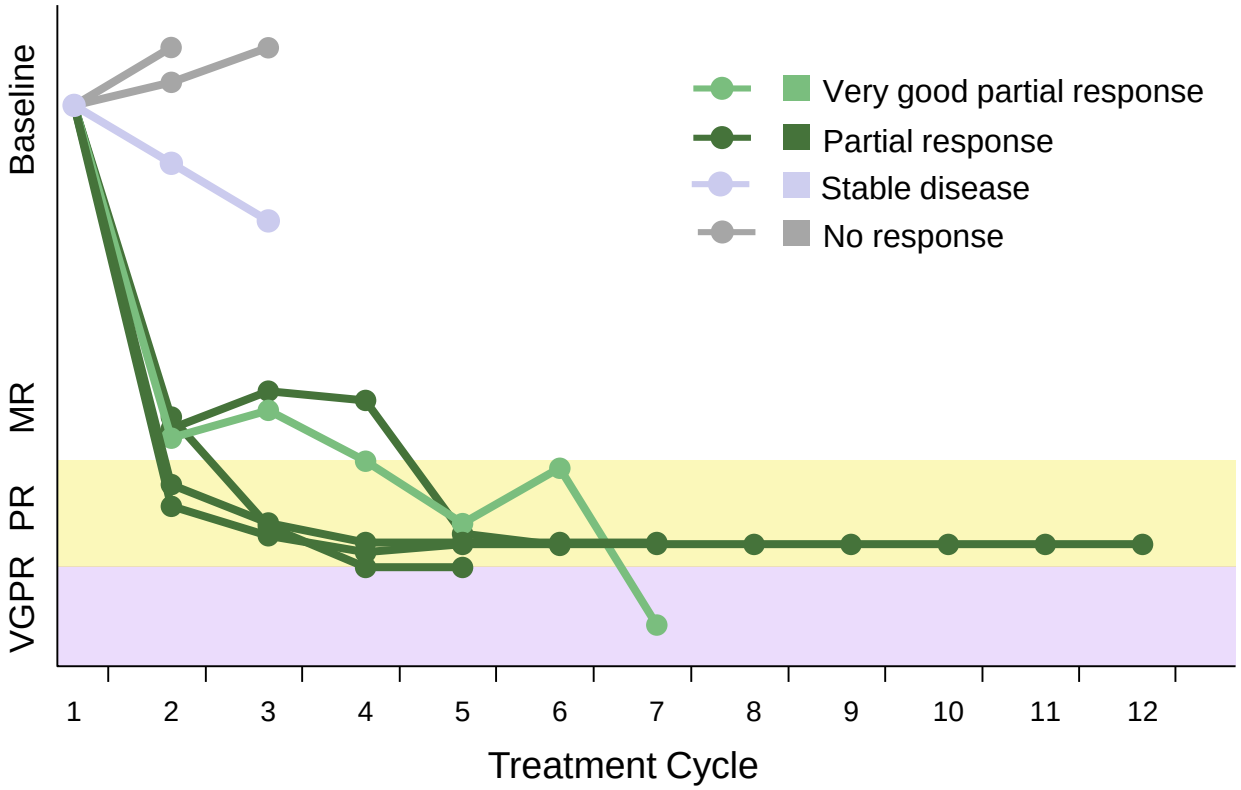

- Phase 2 open-label, single-arm, multicenter study of MP0250 + Velcade® + dexamethasone in patients with refractory and relapsed multiple myeloma (RRMM)
- Study population: MM patients who have received ≥2 lines of therapy, including Velcade® and an IMiD, and have shown no response to most recent therapy or progressed ≤60 days after most recent therapy
- Next readouts: Additional safety and initial efficacy data before end 2018

Study details can be found at clinicaltrials.gov/NCT03136653.

# MP0250 Phase 2 Study in MM Initial Read-out: Promising Signs of Efficacy at initial dose (8mg/kg)

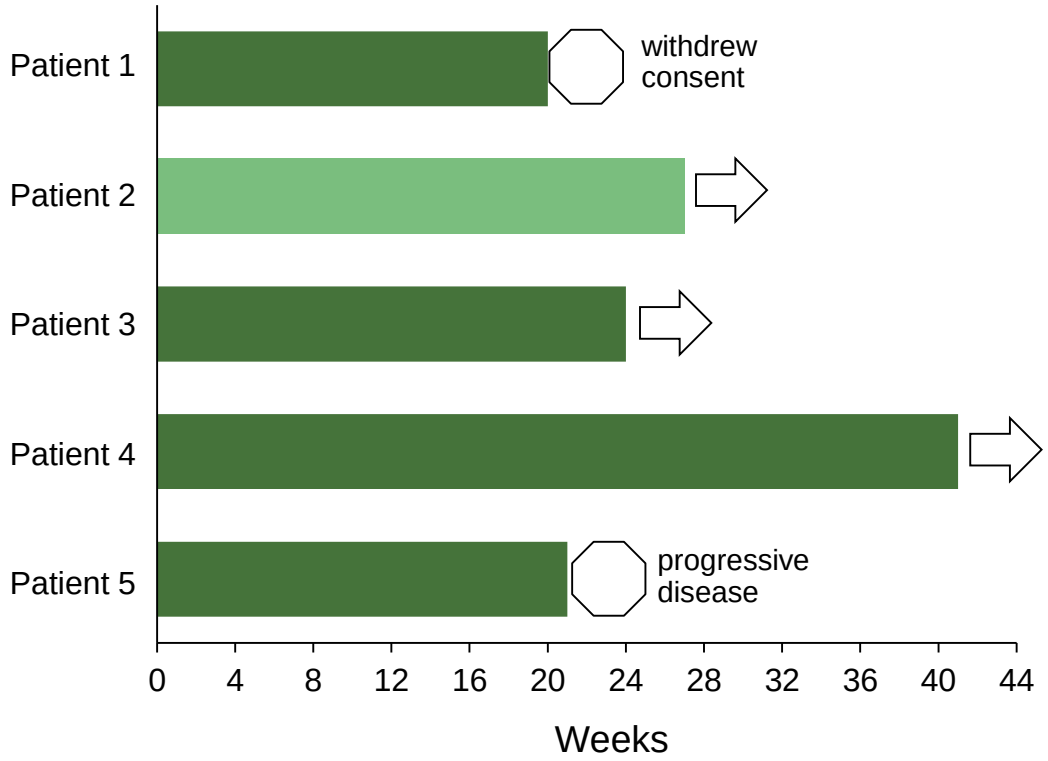
MP0250

## Preliminary results*: Best responses




## Treatment duration*

(5/8 patients with anti-myeloma activity; excludes non-responders)




* Data cut-off: 21 May 2018; Initial dose level: 8mg/kg/3weeks.



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# Unique Potential of MP0250 in MM

MP0250

- Multiple myeloma:
  2nd most common blood cancer
- Global market value ~USD 9.8bn,
  expected to reach > USD 12bn by 2021 [1]

75%

25%

**1st/2nd-line**
n >100,000[1]

IMiD or PI + mAb

PI or IMiD + mAb

Transplant

HGF/
c-MET

*No later-line treatments target these key escape pathways*

**3rd/4th-line**
n ≈30,000[1]

PI + X

IMiD + Y

+ MP0250

**MP0250:**
Potential to become backbone for all later lines

1. Including US/5EU/JP. Datamonitor.



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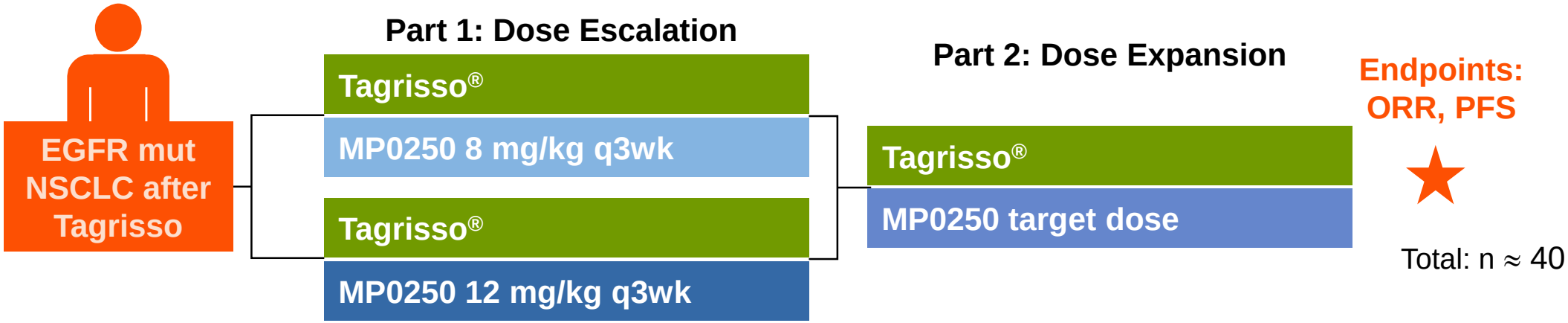
# MP0250 Phase 2 Study in NSCLC

MP0250




- Status: FDA approval Sep 2017 – 1st oncology DARPin® drug candidate in US
- Collaboration with AstraZeneca for Tagrisso® supply
- Next readouts: initial safety in 2018 & initial efficacy 2019

*The study details can be found on clinicaltrials.gov/NCT03418532.

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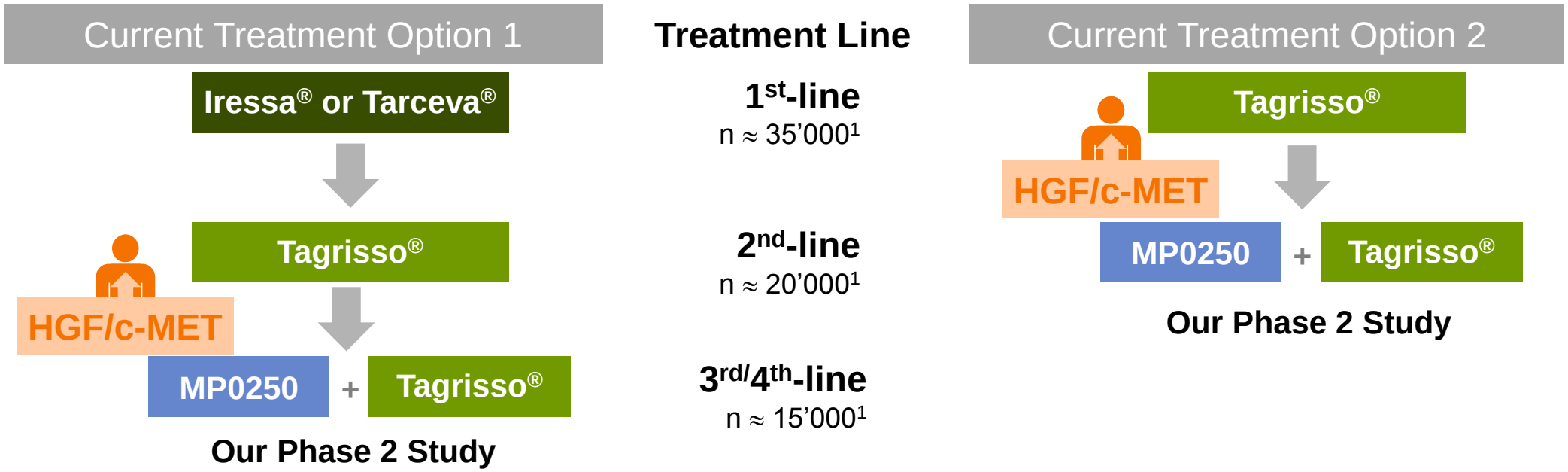
# Unique Potential of MP0250 in EGFR mut NSCLC

MP0250




- NSCLC is leading cause of cancer death
- Activating EGFR mutations are found in ~40% (Asia), ~20% (US), and ~15% (EU) NSCLC[2]
- Global market value (EGFR NSCLC) ~USD 2.8bn, expected to reach >3.5bn by 2023 (5% CAGR)[3]
- No targeted drug approved after patients progress under Tagrisso® treatment

1. Including actively treated, Stage IIIb and Stage IV prevalent cases in US/5EU/JP. Based on Datamonitor; 2. Tang, et al. Oncotarget 2016; 3. Datamonitor

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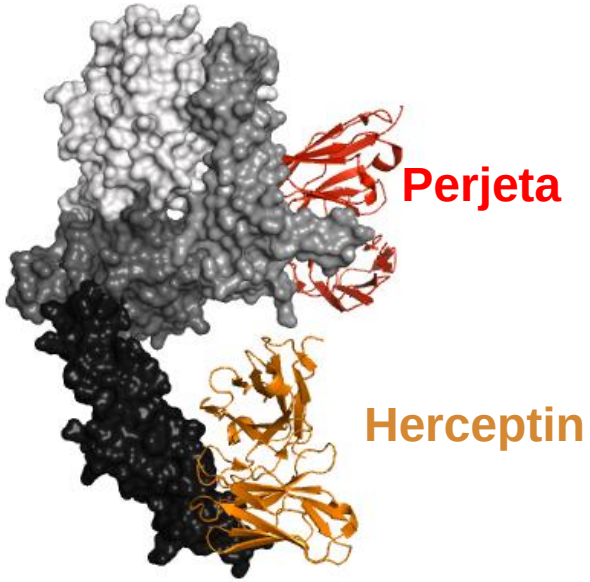
# MP0274 Forces Her2 in Conformational Deadlock, Leading to Cell Death

MP0274

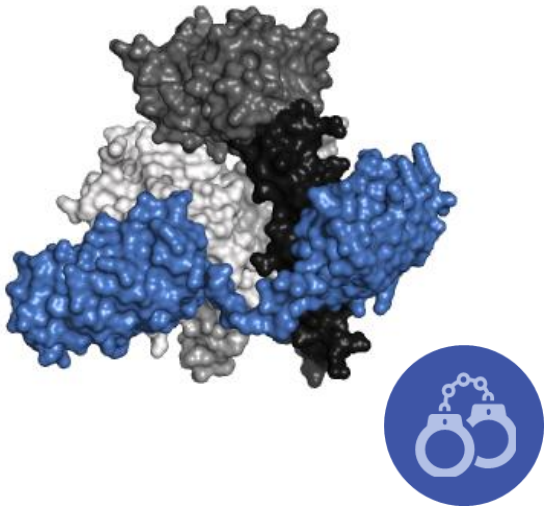
Her2 EC-Domain

## Trastuzumab & Pertuzumab




Herceptin and Perjeta block two distinct Her2 functions

## MP0274 Bi-paratopic DARPin®

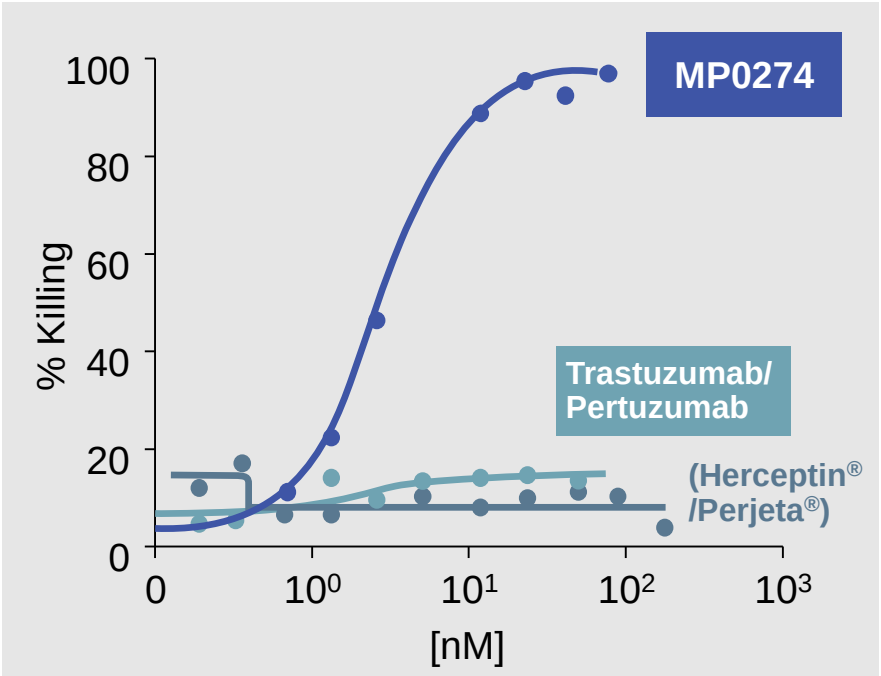


MP0274 handcuffs Her2 into fully inactive conformation*, acting as broad-range allosteric inhibitor

* model picture

## Tumor Cell Apoptosis

BT474




New MoA may help patients who do not adequately respond to current therapies

EC: extracellular

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# MP0274: Phase 1 Study in HER2+ Cancer Patients

MP0274

- **Phase 1, first-in-human, single-arm, multicenter, open-label, repeated-dose, dose escalation study**
  - **assess safety, tolerability and pharmacokinetics of MP0274**
  - in patients with advanced HER2-positive solid tumors
  - with **expansion cohort** at recommended dose to confirm safety and to **assess preliminary efficacy**

- **Study treatment** (estimated enrollment of 46 patients):
  - Dose Escalation
  - Dose Expansion at recommended dose

- **Next readouts:** Initial safety data expected in Q4 2018 and first efficacy data in 2019

*Study details can be found at clinicaltrials.gov/NCT03084926.

 

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# Immuno-Oncology

# MP0310

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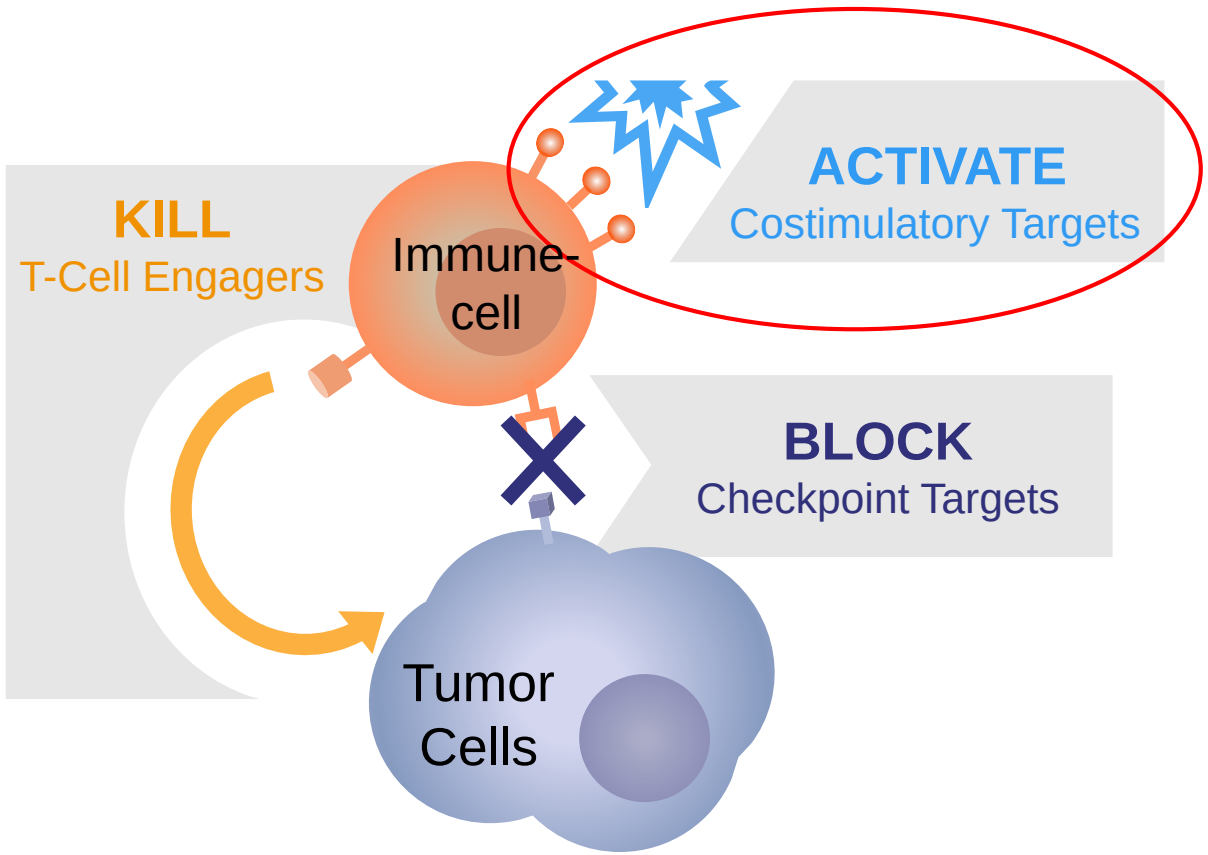
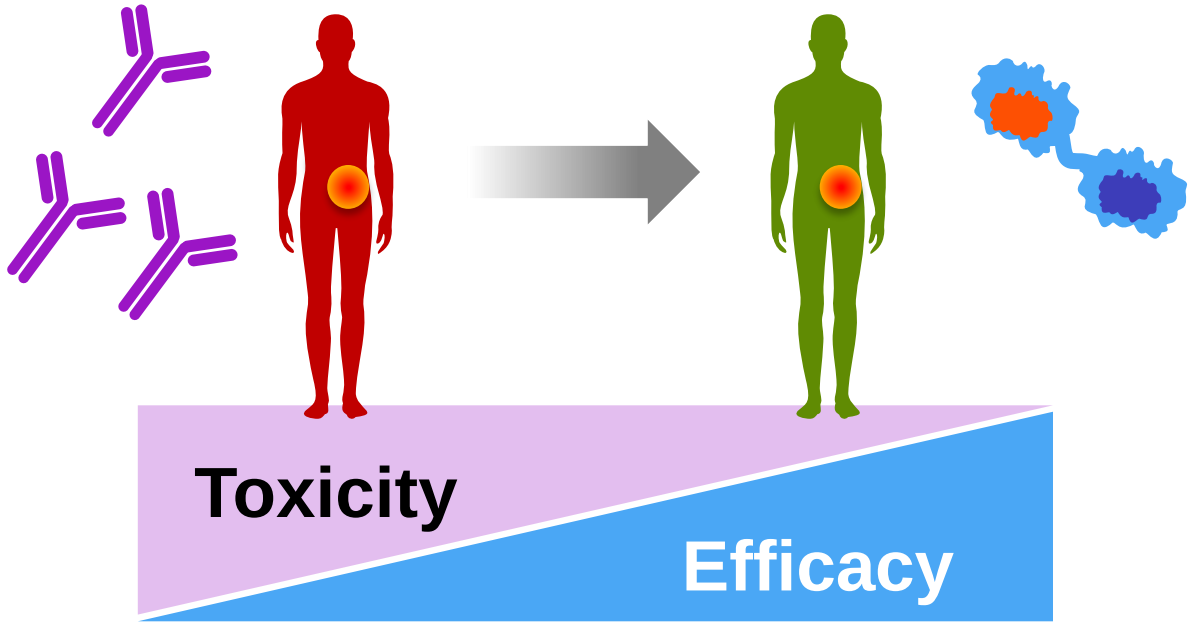
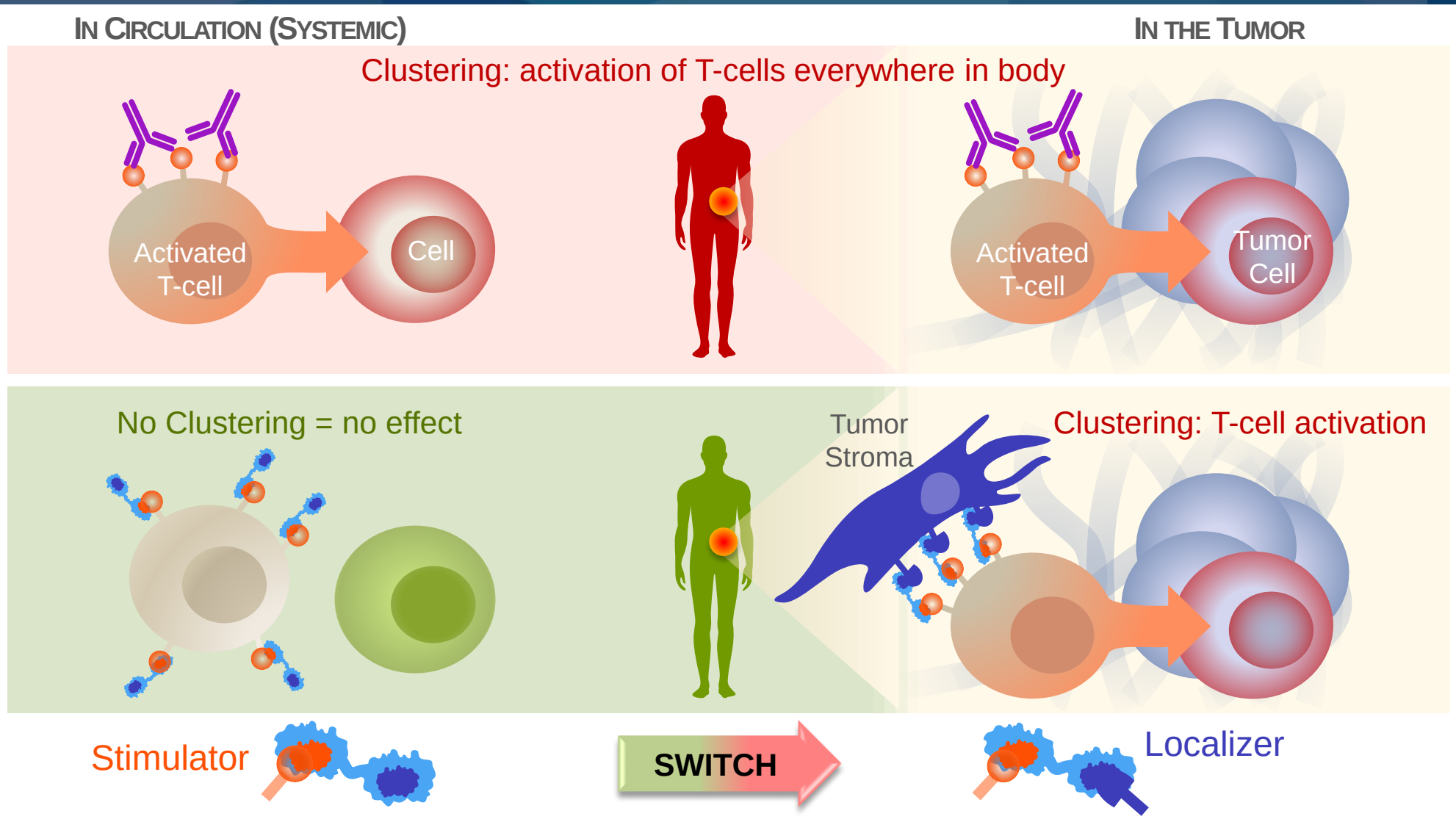
# Improving the Therapeutic Index of IO Agents



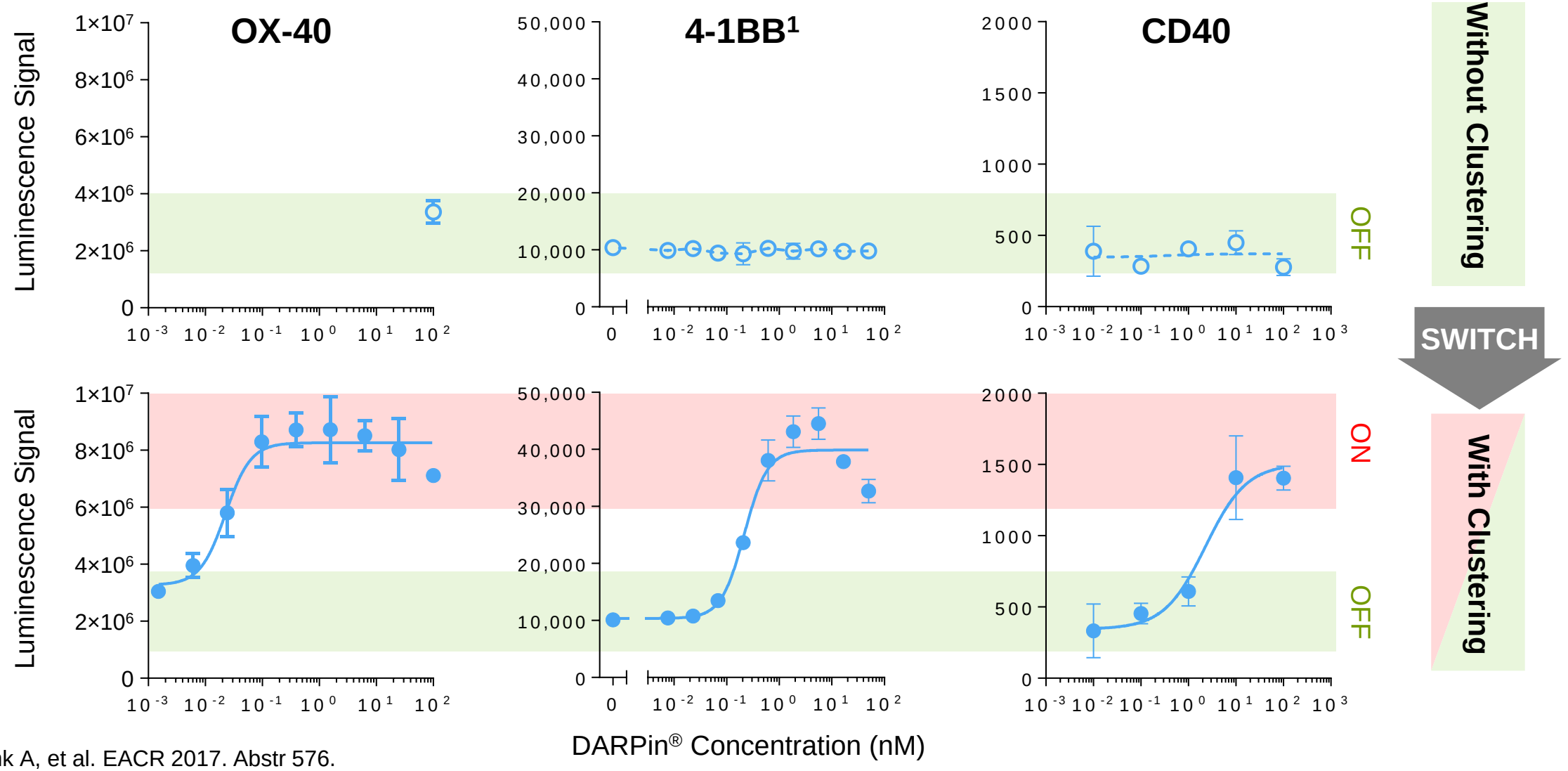




**Tumor localized IO agents may achieve both, reduce systemic toxicity and improve efficacy**

# How do we achieve the improved therapeutic index?

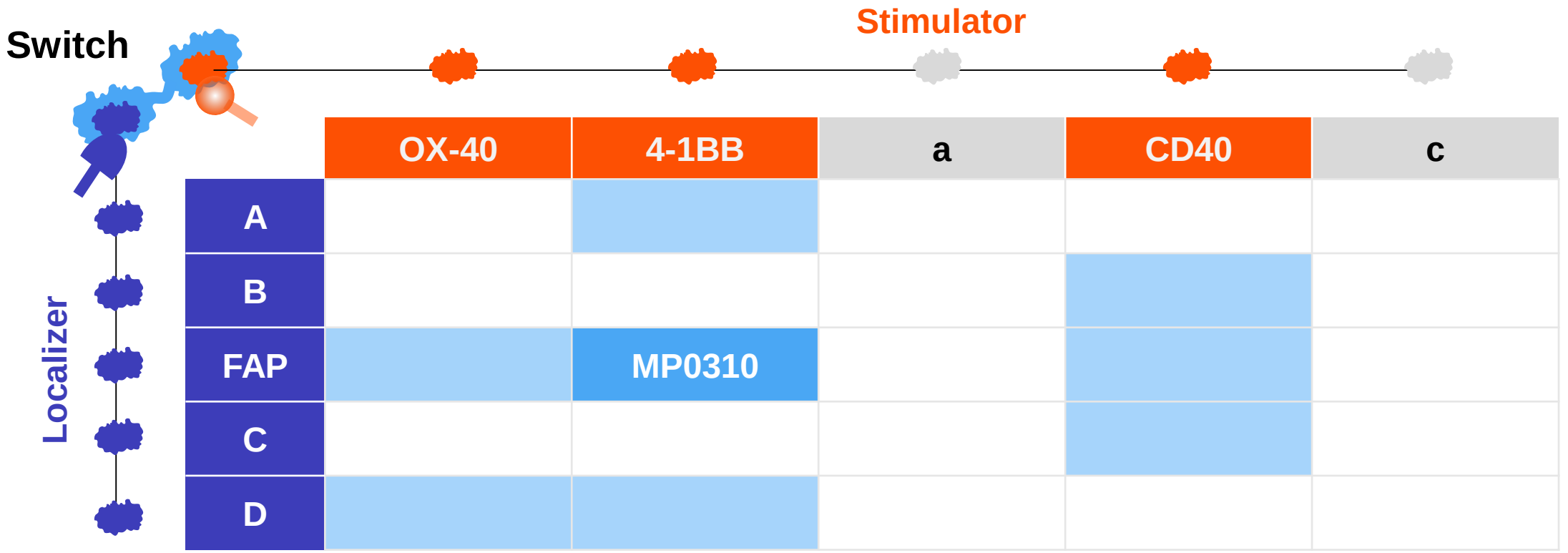


# Therapeutic Design applicable to many Agonists




1. Link A, et al. EACR 2017. Abstr 576.

# DARPin® I/O Platform with Multiple Opportunities: MP0310 as the first DARPin® product candidate




Many DARPin® candidates are under investigation for both solid and liquid tumors (including combinations)

# Ophthalmology

# Abicipar

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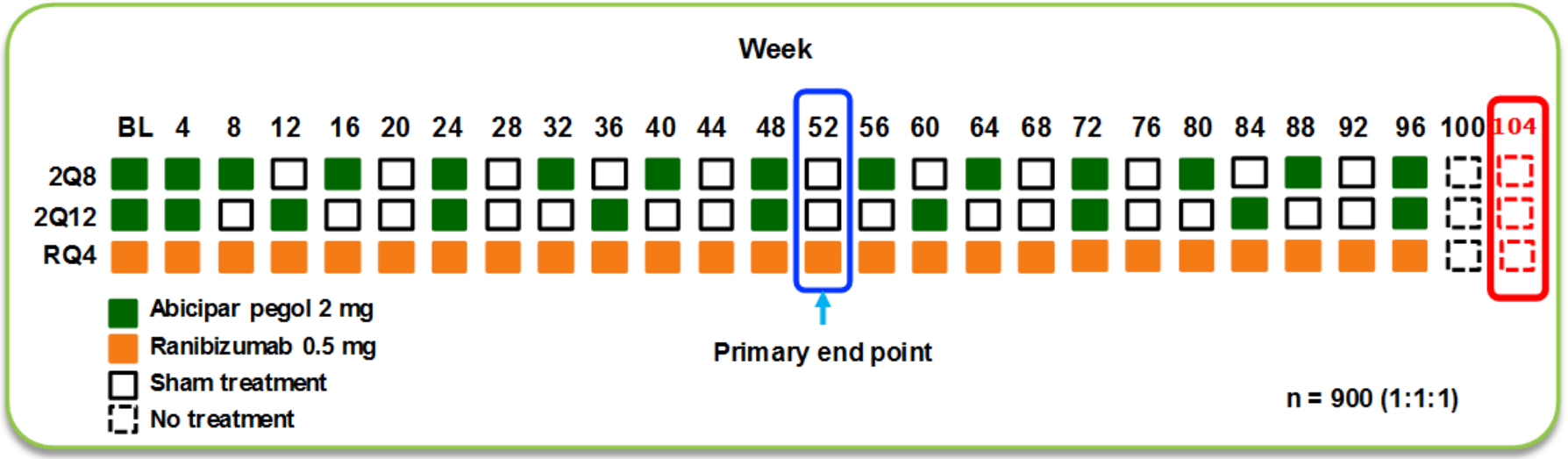
# Phase 3 CEDAR & SEQUOIA Study Design

Abicipar

- **Objective:** To assess the efficacy and safety of abicipar pegol compared with ranibizumab in treatment-naïve patients with neovascular AMD
- **Primary endpoint:** Proportion of patients with stable vision at Week 52*
- **Secondary endpoints:** Mean change from baseline in ETDRS BCVA, mean change from baseline in CRT, proportion of patients with ≥ 15-letter gain at Week 52




AMD: age-related macular degeneration
ETDRS: early treatment diabetic retinopathy study
BCVA: best-corrected visual acuity
CRT: central retinal thickness

*Loss of < 15 ETDRS letters compared to baseline

Source: Allergan presentation, 19 July 2018



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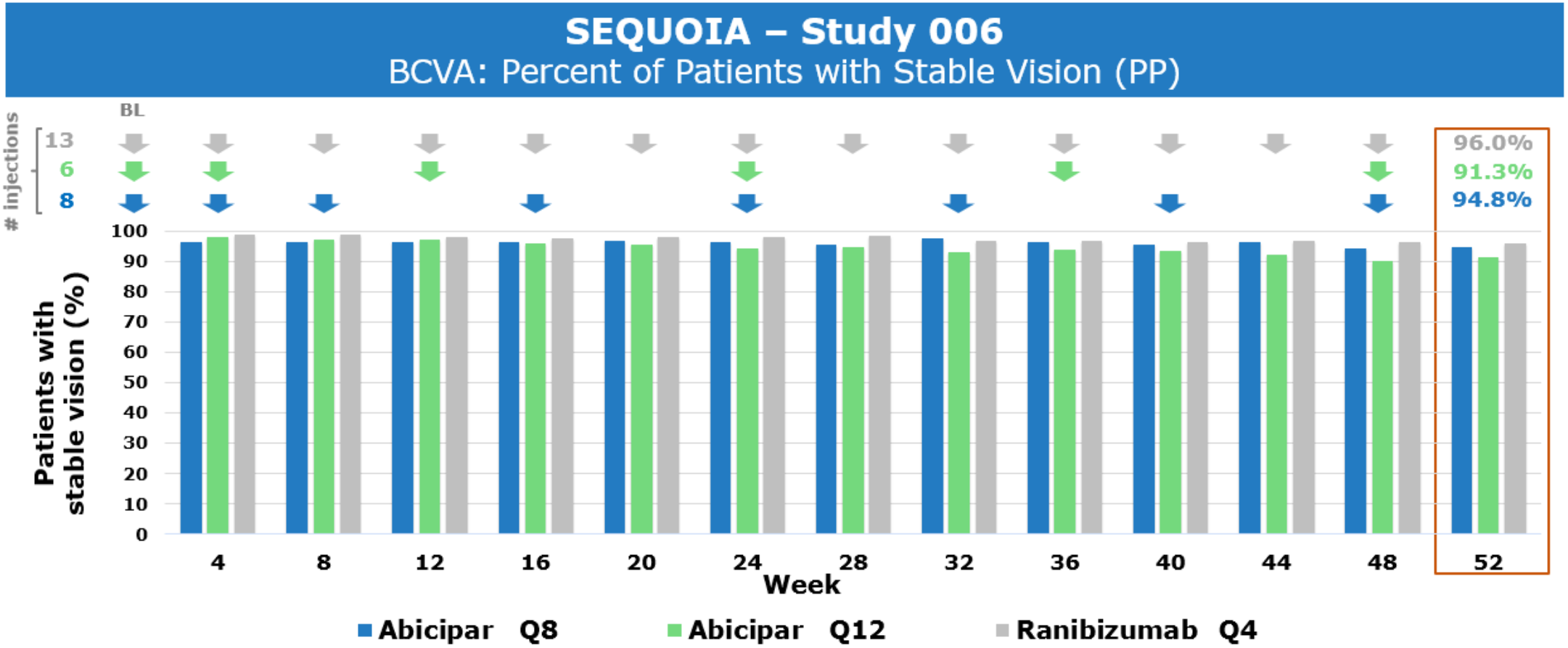
# Primary Endpoint: STABLE VISION Abicipar Q8 and Q12 Non-Inferior to Ranibizumab Q4 With Fewer Injections

**Abicipar**




Source: Allergan presentation, 19 July 2018

PP=Per protocol; BCVA=Best Corrected Visual Acuity; BL= baseline

Allergan

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# Abicipar Dosed Every 8 and Every 12 Weeks Demonstrated Non-Inferiority to Lucentis® Dosed Every 4 Weeks

Abicipar

## Conclusions

√ In both the Sequoia and Cedar studies, abicipar achieved the goal of demonstrating non-inferiority to Q4 ranibizumab for both the Q12 and Q8 dosing regimens.
- >91% of patients had stable vision on the Q12 dosing regimen in each trial

√ Abicipar is the first and only anti-VEGF therapy to consistently extend duration of effect beyond 8 weeks to a full 12 weeks vs monthly Lucentis
- Undertreatment resulting from the "Treat and Extend" treatment paradigm results in sub-optimal vision gains and loss of vision gains over time

√ Overall incidence of adverse events was similar among the 3 treatment arms
- Incidence of intraocular inflammation events were 15.7% and 15.3% for abicipar Q8 and abicipar Q12, compared to 0.6% for ranibizumab Q4 in Sequoia, and were 15.1% and 15.4% compared to 0% for ranibizumab in Cedar

Abicipar continues to have the opportunity to be the first and only true long acting anti-VEGF
- Allergan plans to file abicipar with the FDA in 1H 2019 pending the pre-BLA meeting with the FDA
- Allergan continues to work on its further optimized formulation with the goal of minimizing inflammation

Source: Allergan presentation, 19 July 2018





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# Financial Results H1 2018

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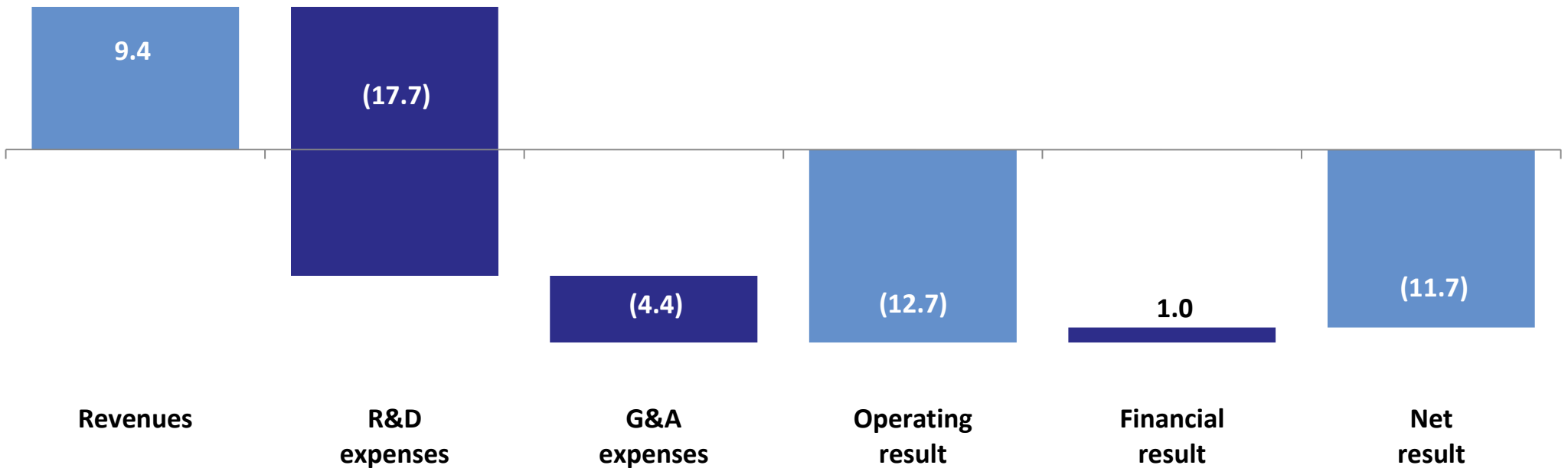
# Financial Summary

| *(CHF million; as per IFRS)* | ***H1 2018*** | *H1 2017* | ***change*** |
|---|---|---|---|
| **Revenues** | **9.4** | 6.0 | **3.4** |
| **Total expenses**[1] | **(22.1)** | (22.7) | **0.6** |
| **Operating result – EBIT** | **(12.7)** | (16.7) | **4.0** |
| **Net financial result** | **1.0** | (2.7) | **3.7** |
| **Net result** | **(11.7)** | (19.4) | **7.7** |
| **Basic net result per share (in CHF)** | **(0.56)** | (0.93) | **0.37** |
| **Net cash used in operations** | **(19.4)** | (20.5) | **1.1** |
| **Cash balance** | **122.4**[2] | 156.9[3] | **(34.5)** |

[1] Thereof non-cash costs of CHF 3.0m in H1 2018and CHF 2.6m in H1 2017
[2] Including CHF 9.8 million short-term time deposits
[3] Including CHF 30.5 million short-term time deposits

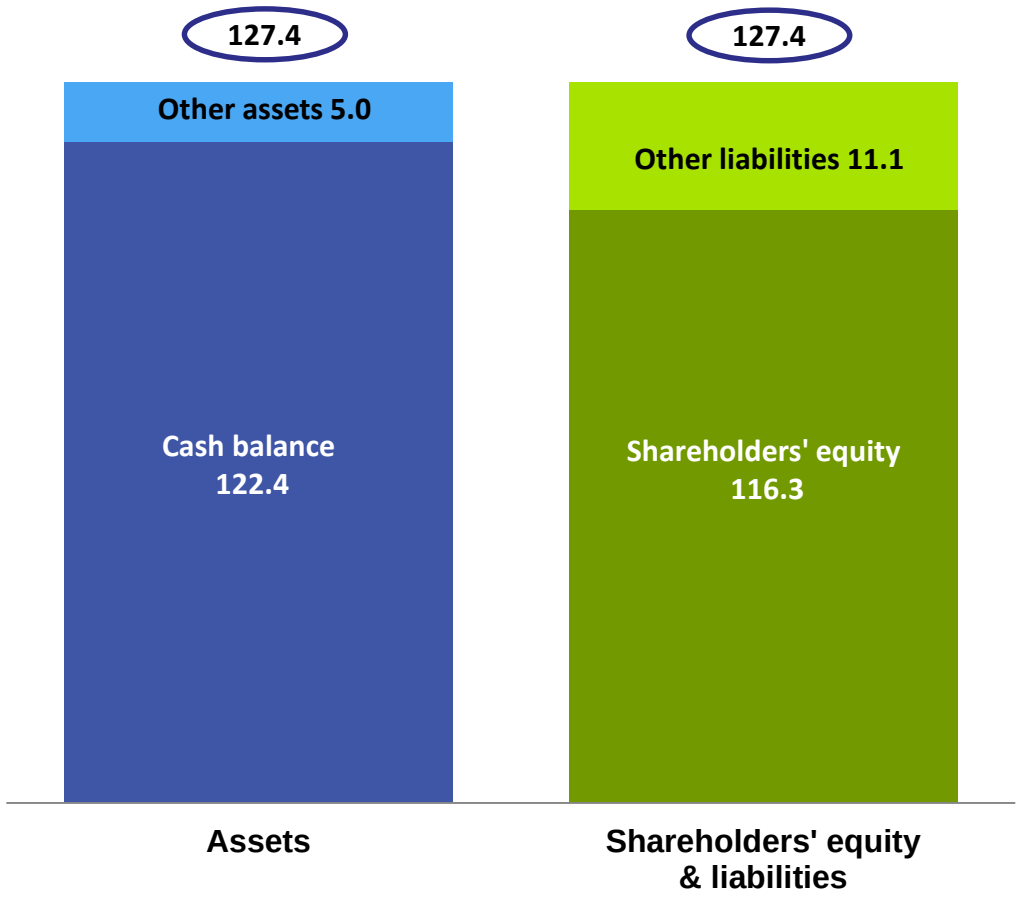
# P&L De-composition

*P&L de-composition per line item (CHF million)*



# Balance Sheet

*Balance sheet as of June 30, 2018 (CHF million)*

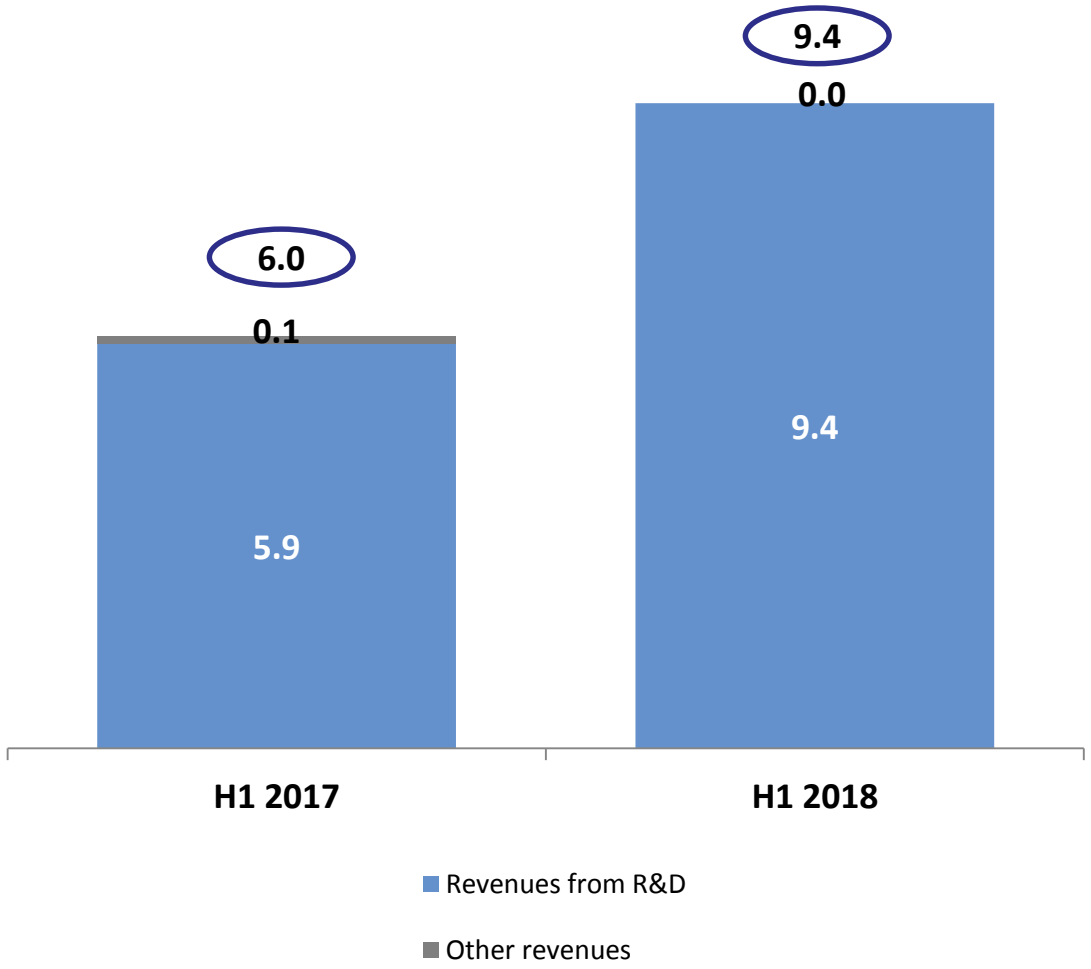



*Comments*

- Continuing strong balance sheet
- CHF 122.4 million cash balance (incl. time deposits) – 96% of total assets
- Solid equity base with CHF 116.3 million
- Debt free
- Following implementation of IFRS 15,
  CHF 18.4 million deferred revenues as of Dec. 31, 2017:
  - presented in equity for CHF 9.0 million
  - recognized into revenue for CHF 9.4 million in H1 2018

# Revenues

*In CHF million*

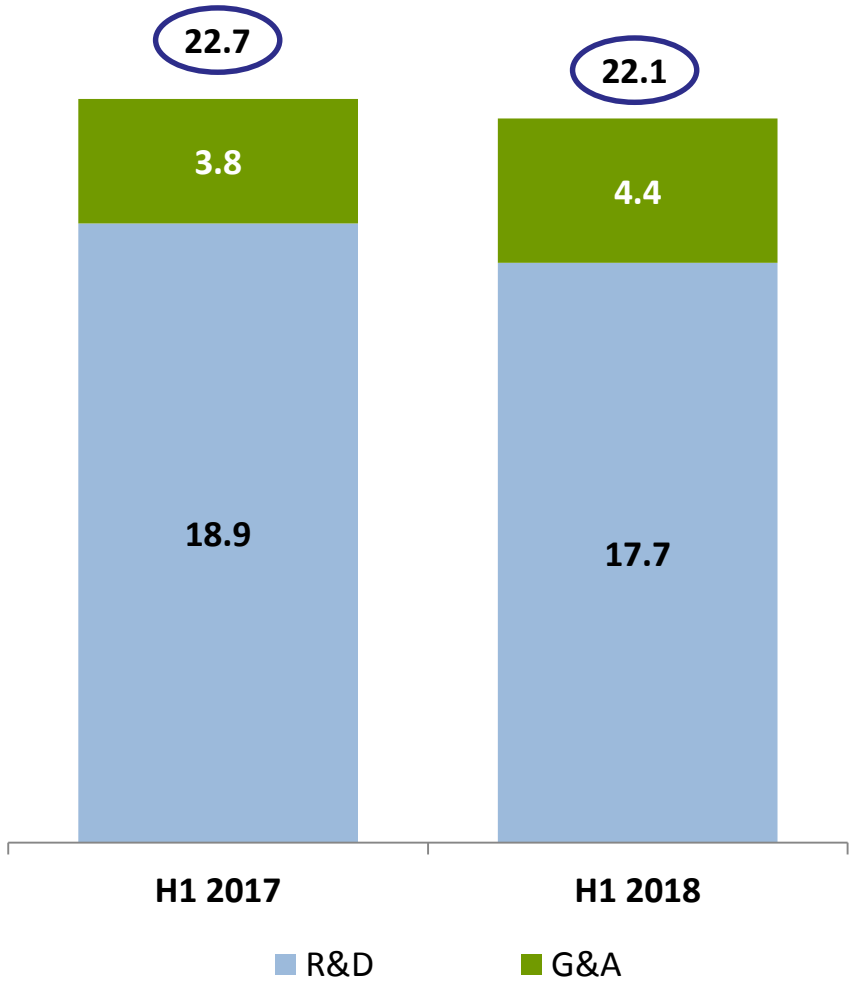



*Comments*

- CHF 9.4 million revenues recognized out of deferred revenues position, following implementation of IFRS 15
- Following implementation of IFRS 15, no deferred revenues left to be recognized as revenue in future periods

# Operating Expenses

*in CHF million (incl. depreciation & amortization)*

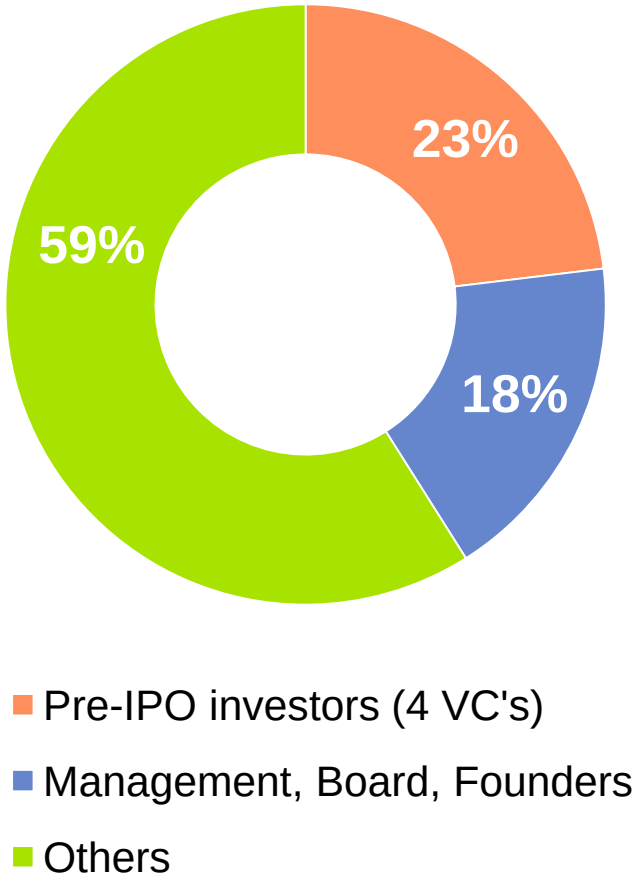



*Comments*

- Expense development in line with expectations
- In H1 2018 main expense positions and drivers were:
  - Investments in pre-clinical and clinical development of proprietary oncology assets (MP0250, MP0274, MP0310)
  - Personnel cost, reflecting ongoing build-out and growth of organization
  - CHF 3.0 million non-cash effective costs (H1 2017: CHF 2.6 million)

# Shareholder Structure

*Shareholder structure as of June 30, 2018*




*Highlights*

- VC holdings halved vs. end 2016 to 23%
- Listed on SIX Swiss Exchange (SIX: MOLN)
- Included in key indices: SPI, SPI Extra, SXI Life Sciences and SXI Bio+Medtech
- 21,180,138 shares outstanding
- Ca. CHF 486 million market cap. as of June 30, 2018
- No lock-up restrictions in place
- Formal free float as per SIX definition: 84%

# Financial Guidance for Full-Year 2018

- Total expenses at lower end of indicated CHF 50-60 million range,
  of which around CHF 6 million non-cash effective costs

- Capital expenditures of ca. CHF 3 million come on top

- No guidance on net cash flow;
  timelines and potential milestones payments with partnerships not disclosed

- Guidance subject to progress and changes of pipeline

# Outlook 2018 & Beyond

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# Key Messages H1/2018

- Successful transition from DARPin® platform into **clinical oncology company**:
  - **MP0250** (Phase 2) demonstrated initial activity in MM and is progressing in NSCLC (EGFR-mut)
  - MP0274 (Phase 1) ongoing in Her2+ cancers
  - MP0310 selected as 1st development candidate (preclinical) from **I/O DARPin® toolbox**
- **Abicipar** Phase 3 in nAMD progressing with partner Allergan:
  - Top-line data demonstrated **non-inferiority of abicipar Q12 vs Lucentis Q4 dosing**
  - Further optimized formulation is being tested to reduce inflammation (MAPLE trial)
- Financed into 2020 (excluding any abicipar-related proceeds), capturing key value inflection points

➢ Keep on forward integrating towards late-stage development and the market

# Multiple Value Inflection Points Ahead

| | 2018 | 2019 | 2020 |
|---|---|---|---|
| **Abicipar** | **nAMD: 1-y Ph 3 efficacy** ✓ | Data from further optimized formulation (MAPLE trial) H1/19<br>FDA filing planned for H1/19<br>DME: Ph 3 expected start | nAMD: expected launch |
| **MP0250** | MM: initial efficacy<br>NSCLC: initial safety | MM: efficacy<br>NSCLC: initial efficacy | NSCLC: efficacy |
| **MP0274** | Initial safety | Initial efficacy | |
| **MP0310** | Preclinical data | FIH | |

Funding into 2020 (excl. any abicipar related proceeds)

 

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# Thank you

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# Questions?

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# Appendix

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# Income Statement

| *(CHF million, as per IFRS)* | ***H1 2018*** | *H1 2017* | *Change* |
|---|---|---|---|
| **Revenues** | **9.4** | 6.0 | 3.4 |
| **R&D expenses[1]** | **(17.7)** | (18.9) | 1.2 |
| **G&A expenses[2]** | **(4.4)** | (3.8) | (0.6) |
| **Operating Loss** | **(12.7)** | (16.7) | 4.0 |
| **Net finance expenses** | **1.0** | (2.7) | 3.7 |
| **Net Loss** | **(11.7)** | (19.4) | 7.7 |

[1] Thereof non-cash costs of CHF 1.7m in H1 2018 and CHF 1.6m in H1 2017
[2] Thereof non-cash costs of CHF 1.3m in H1 2018 and CHF 1.0m in H1 2017

# Cash Flow Statement

| *(CHF million, as per IFRS)* | ***H1 2018*** | *H1 2017* | *Change* |
|---|---|---|---|
| **Net cash used in operations** | **(19.4)** | (20.5) | 1.1 |
| **Net cash used in investing** | **(20.1)** | (8.1) | (12.0) |
| **Net cash from financing** | **0.2** | 0.3 | (0.1) |
| **Exchange result on cash positions** | **0.7** | (2.8) | 3.5 |
| **Net decrease in cash & cash equivalents** | **(38.6)** | (31.1) | (7.5) |

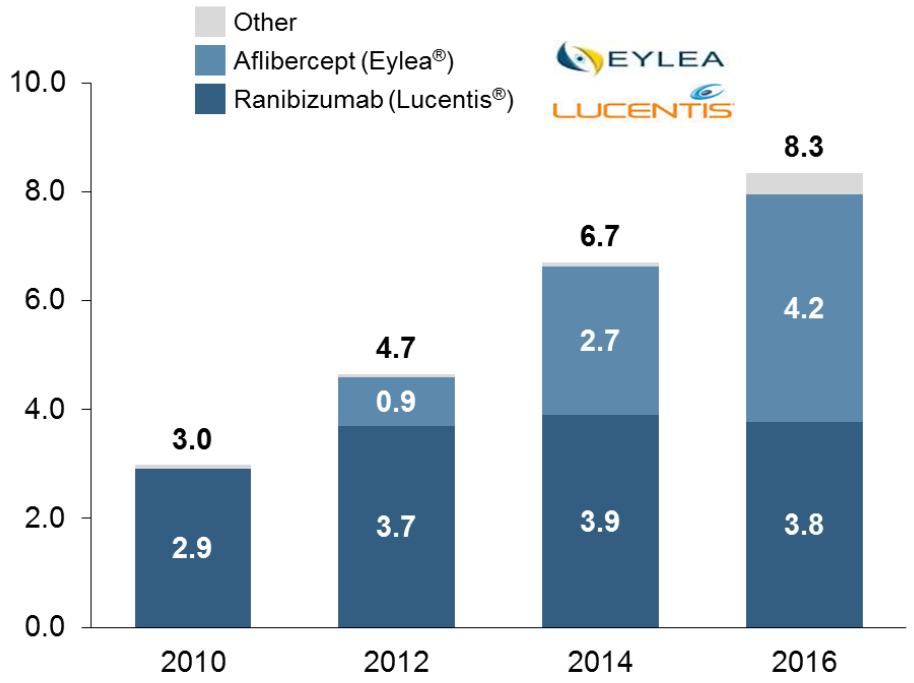
# Balance Sheet

| *(CHF million, as per IFRS)* | ***30 June 2018*** | *31 Dec 2017* | *30 June 2017* |
|---|---|---|---|
| **Non-current assets** | **1.6** | 1.9 | 2.2 |
| **Other current assets[1]** | **3.4** | 1.5 | 1.9 |
| **Cash balance (incl. time deposits)** | **122.4** | 141.0 | 156.9 |
| **Shareholders' equity** | **116.3** | 116.7 | 118.3 |
| **Non-current liabilities[2]** | **4.4** | 13.6 | 27.8 |
| **Current liabilities[3]** | **6.7** | 14.1 | 14.9 |

[1] Prepayments and other assets, trade and other receivables
[2] Thereof deferred revenues of CHF nil in 1H 2018, CHF 9.5m in FY2017 and CHF 21.6m in 1H 2017
[3] Thereof deferred revenues of CHF nil in 1H 2018, CHF 8.9m in FY2017 and CHF 10.5m in 1H 2017

# Economic Potential of Abicipar Collaboration

- Total of **USD 360m in potential future milestones**
  - USD 210m development milestones pre launch
  - Additional USD 150m sales-based milestones
- Tiered royalties: Low double-digit to mid-teens
- Attractive >USD 8 billion market,
  reducing the injection frequency can lead to rapid market uptake (Eylea®)
- Significant potential **funding source to fuel growing oncology pipeline**




**Global Wet AMD and DME Market Size (USDbn)**

Source: Evaluate Pharma®, Accessed 27 Apr 2015;
Avastin® is used off label.

# Experienced Management Team & Board of Directors

## Executive Management

**Dr. Patrick Amstutz, CEO**

- Co-founder, former CBO & COO
- **Member of the Board of Directors**
- PhD in molecular biology from UZH

**Dr. Andreas Harstrick, CMO, MD**

- 30 years of experience in oncology
- Developed multiple mAb oncology products
- Senior positions at Merck-Serono, Imclone, Eli Lilly

**Dr. Michael Stumpp, COO**

- Co-founder
- PhD and postdoc from UZH; research in Tokyo, London

**Andreas Emmenegger, CFO**

- Former CFO Glycart, Finance Roles at Roche
- >20 years experience as CFO of private & listed companies and in fund raising, IPOs

**Dr. Pamela Trail, CSO**

- >30 years of experience in directing cancer drug discovery at leading global pharma companies

## Board of Directors

**Bill Burns, Chairman**

- Former CEO of Roche Pharmaceuticals
- Former board member of Roche, Genentech, Chugai Pharmaceuticals, Shire

**Göran Ando, Vice Chairman**

- Former Chairman, Novo Nordisk
- Former CSO, Pharmacia

**Gwen Fyfe**

- Former VP, Oncology Development at Genentech

**Steven H. Holtzman**

- President and CEO, Decibel Therapeutics
- Former EVP, Biogen

**William “Bill” Lee**

- EVP Research, Gilead

**Petri Vainio**

- Managing Director, Essex Woodlands Ventures

# IR Agenda

| ***Date*** | ***Event*** |
|---|---|
| November 1, 2018 | Q3 2018 Management Statement |
| December 6, 2018 | R&D  Day in New York |
| February 7, 2019 | Publication of Full-year Results 2018 (unaudited) |
| March 15, 2019 | Expected Publication of Annual Report 2018 |
| April 16, 2019 | Annual General Meeting |

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