



Biopharma R&D pipeline update

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Objective

Becoming a global specialty innovator in **Immunology** and **Oncology**



Strategy

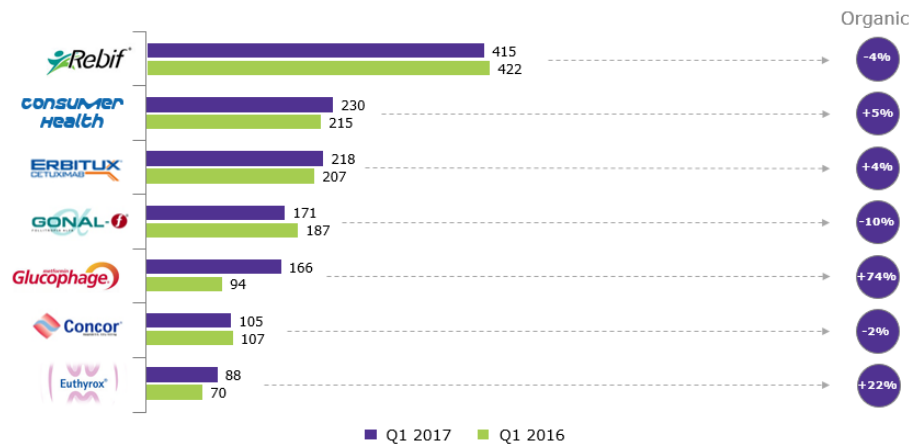
On track to deliver on pipeline ambition: 2bn EUR by 2022

Deliver the pipeline



Funding for growth

Q1 2017 organic sales growth [%] by key franchise/products [€ m]



- **Organic growth** for 23 consecutive quarters
- Commitment to at least **stable organic sales** until 2018

Agenda

Innovation focused on two major areas: **Immunology** + **Oncology**



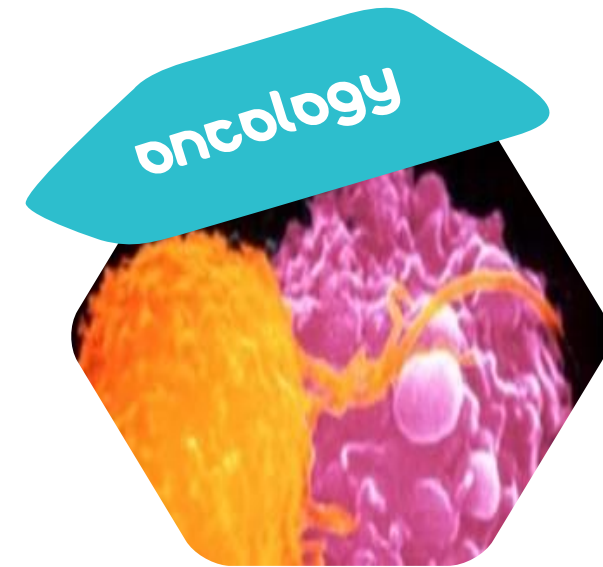
Cladribine Tablets

Evobrutinib



Avelumab

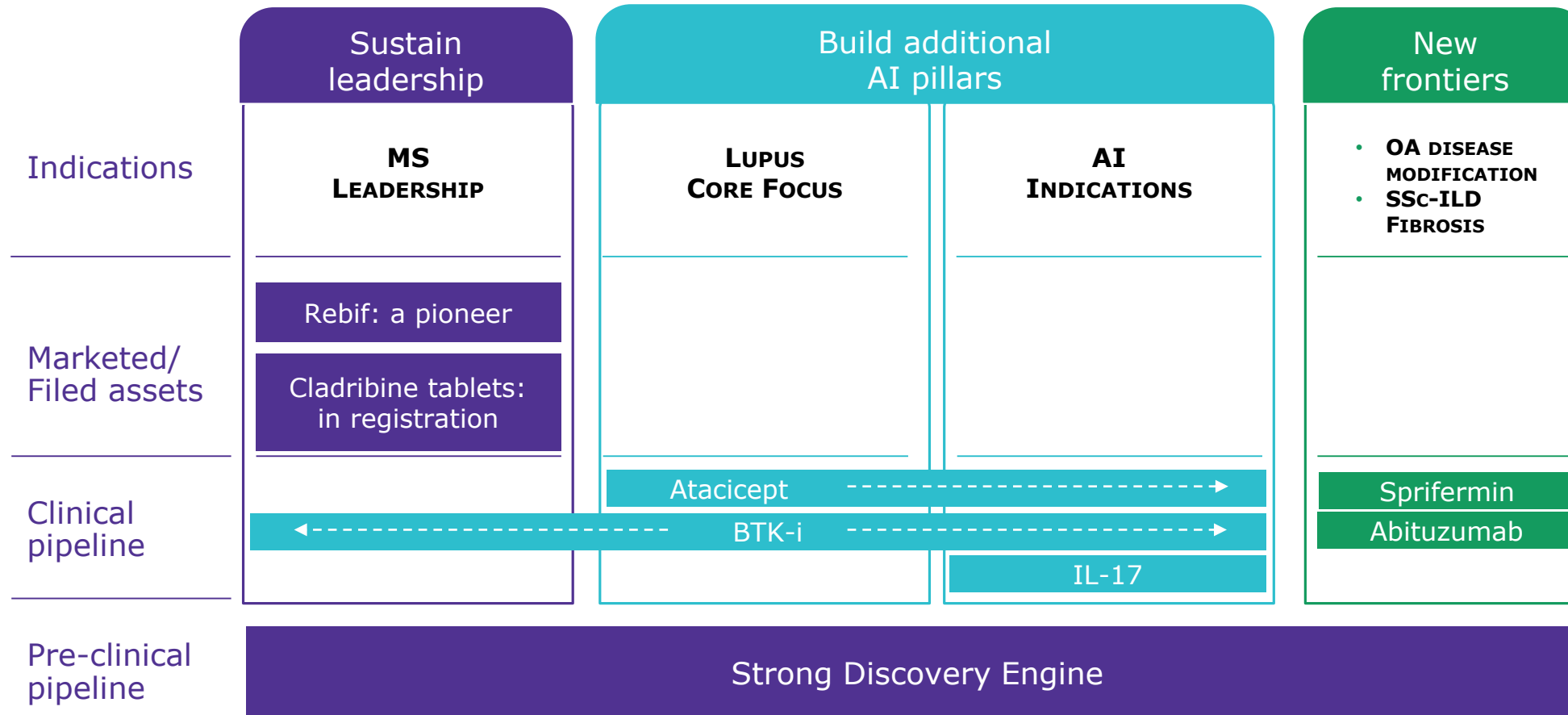
IO Bi-functionals



DNA-Damage Response
Portfolio (DDR)

Immunology

Strategy anchored on leadership in selected disease areas



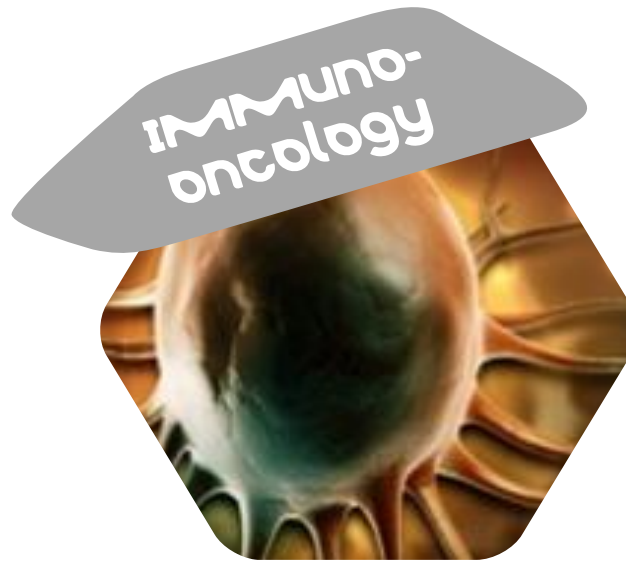
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Innovation focused on two major areas: **Immunology** + **Oncology**



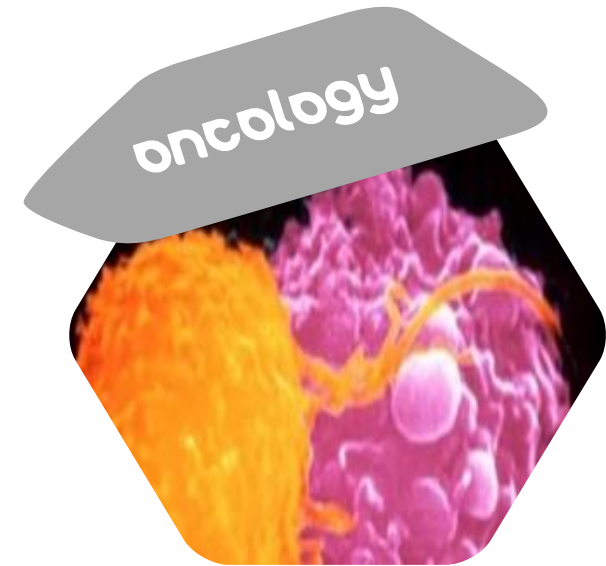
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Evobrutinib



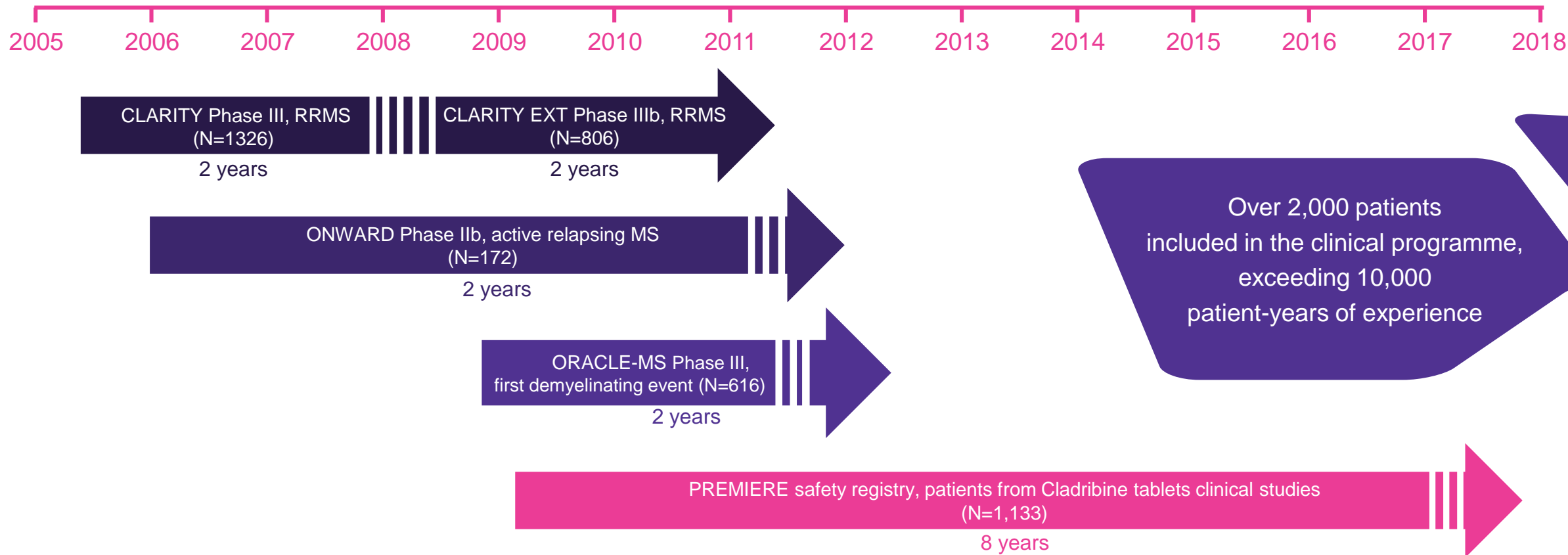
Avelumab

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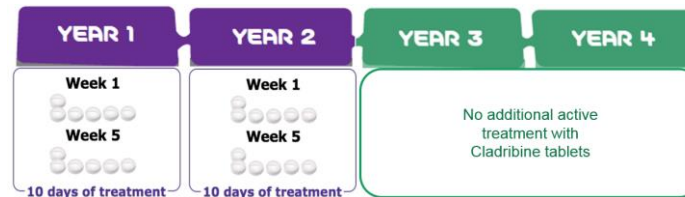
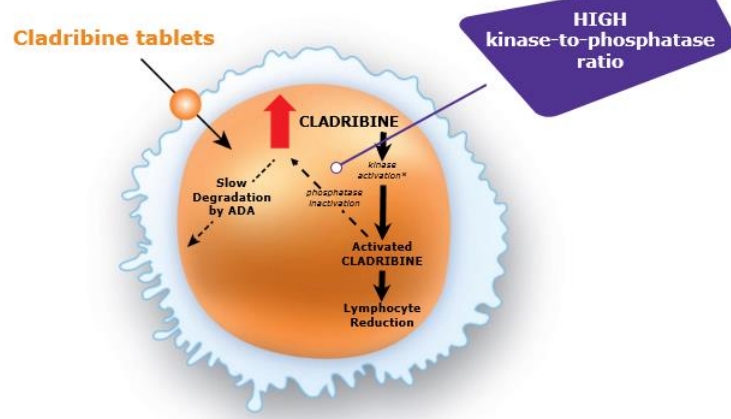
**DNA-Damage Response
Portfolio (DDR)**

Cladribine tablets supported by 10,000 patient years of experience collected over 13 years including an 8 year safety registry



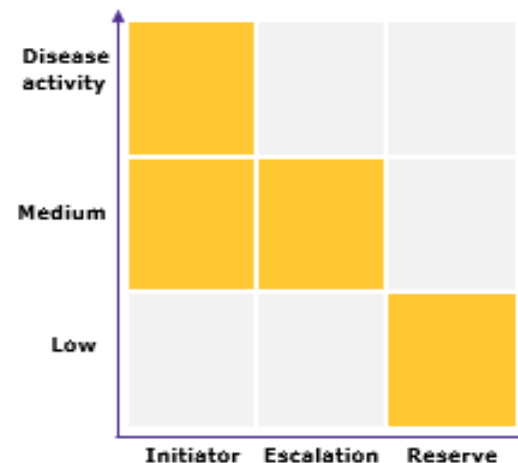
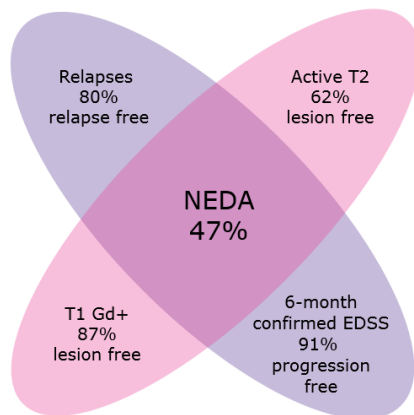
Cladribine tablets could become a relevant therapeutic option in RMS¹

Unique targeted mechanism of action



Unique posology

Efficacy profile²



Focus on patients with high-disease activity

¹ As announced on July 18, 2016, the EMA has accepted for review the Marketing Authorization Application (MAA) of Cladribine Tablets for the treatment of relapsing-remitting multiple sclerosis. | ² NEDA was defined as no relapses, no 6-month confirmed EDSS progression and no new T1 Gd+ lesions and no active T2 lesions on cranial MRI. *Post hoc* analysis EDSS, Expanded Disability Status Scale; Gd+, gadolinium-enhancing; MRI, magnetic resonance imaging; NEDA, no evidence of disease activity Giovanni G et al. Lancet Neurol 2011;10:329-37

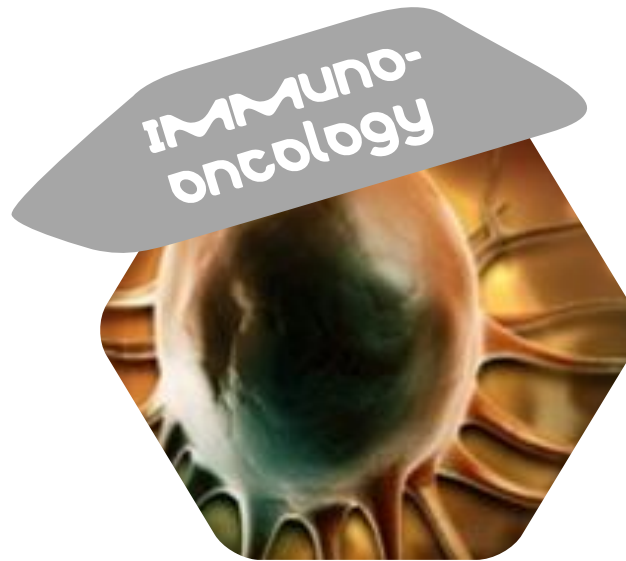
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Innovation focused on two major areas: **Immunology** + **Oncology**



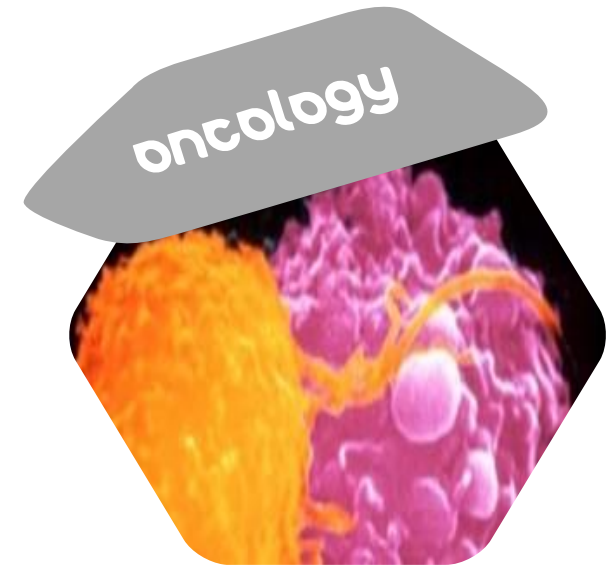
Cladribine Tablets

Evobrutinib



Avelumab

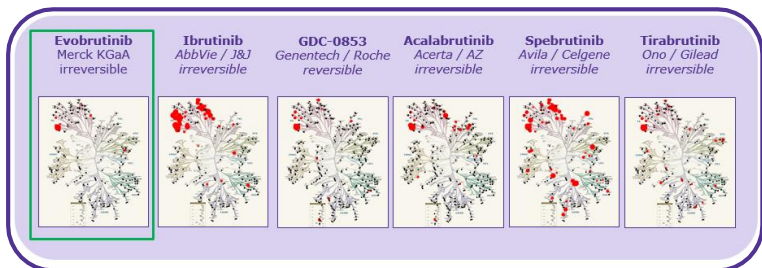
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**DNA-Damage Response
Portfolio (DDR)**

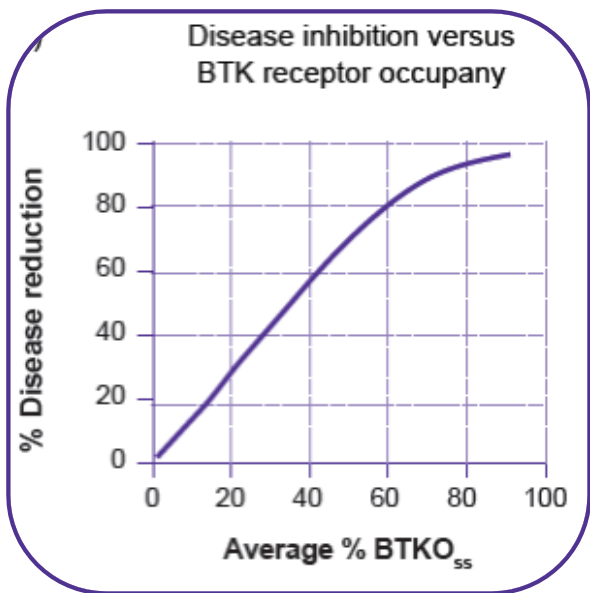
Evobrutinib

Highly selective BTK-i to be explored as chronic therapy



Safety: promising kinase selectivity minimizing off-target effects¹

- Greater selectivity vs. in-class competitors in kinase screen (>270 kinases)
- Besides BTK, two more kinases inhibited (vs. 25 off-target kinases by others)
- Kinase selectivity may result in lower AE rate vs. existing treatments

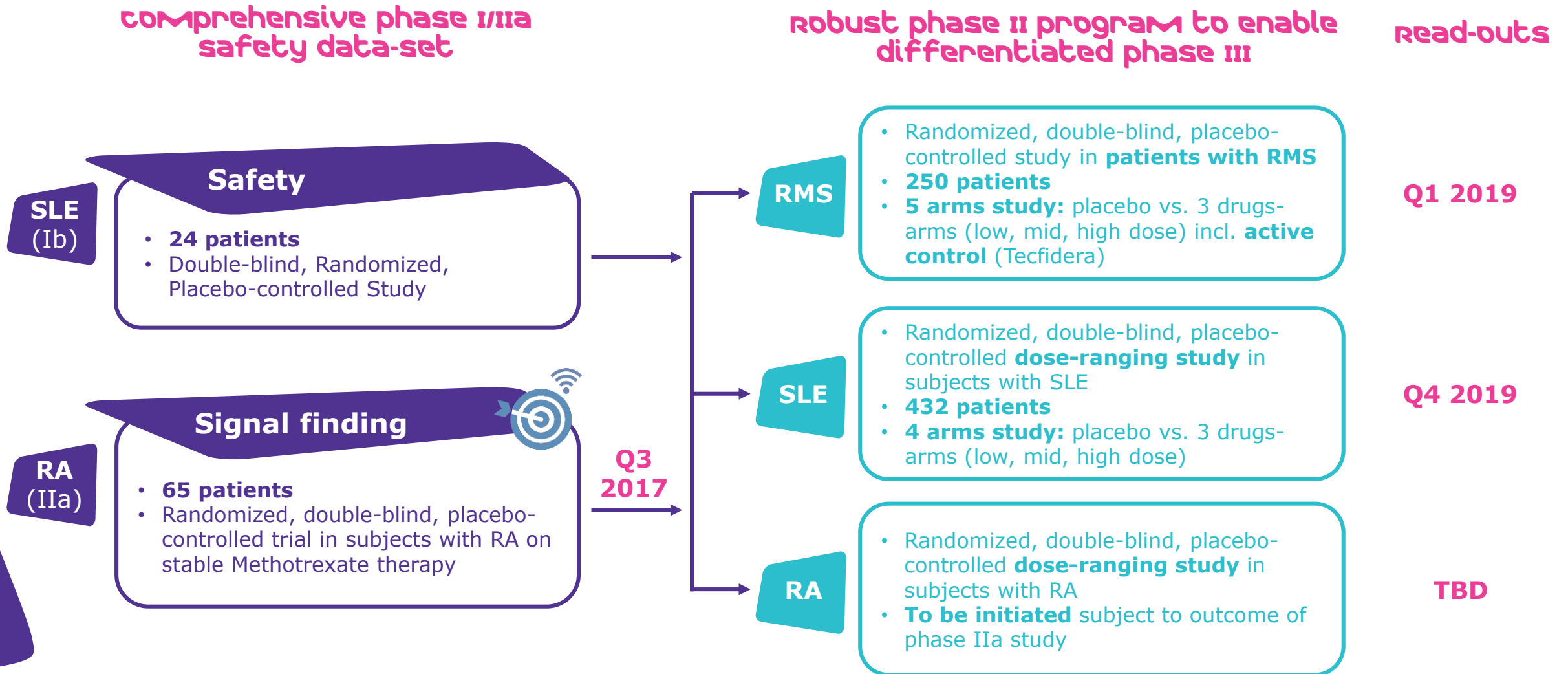


Efficacy: oral, highly efficacious in pre-clinical models¹

- Evobrutinib (irreversible antagonist) inhibiting signal transduction until protein is naturally degraded (no B-cell depletion)
- Occupancy/efficacy correlation: average BTK occupancy of >80% correlated with near complete inhibition of disease activity¹
- Clinical benefit of addressing B cell biology demonstrated by anti-CD20 targeting agents
- Insights from phase IIa trial (RA) leveraged in broad clinical development program (three phase II trials ongoing in MS, SLE, and RA)

Evobrutinib

Comprehensive development plan across immune-mediated diseases



Agenda

Innovation focused on two major areas: **Immunology** + **Oncology**



Cladribine Tablets

Evobrutinib



Avelumab

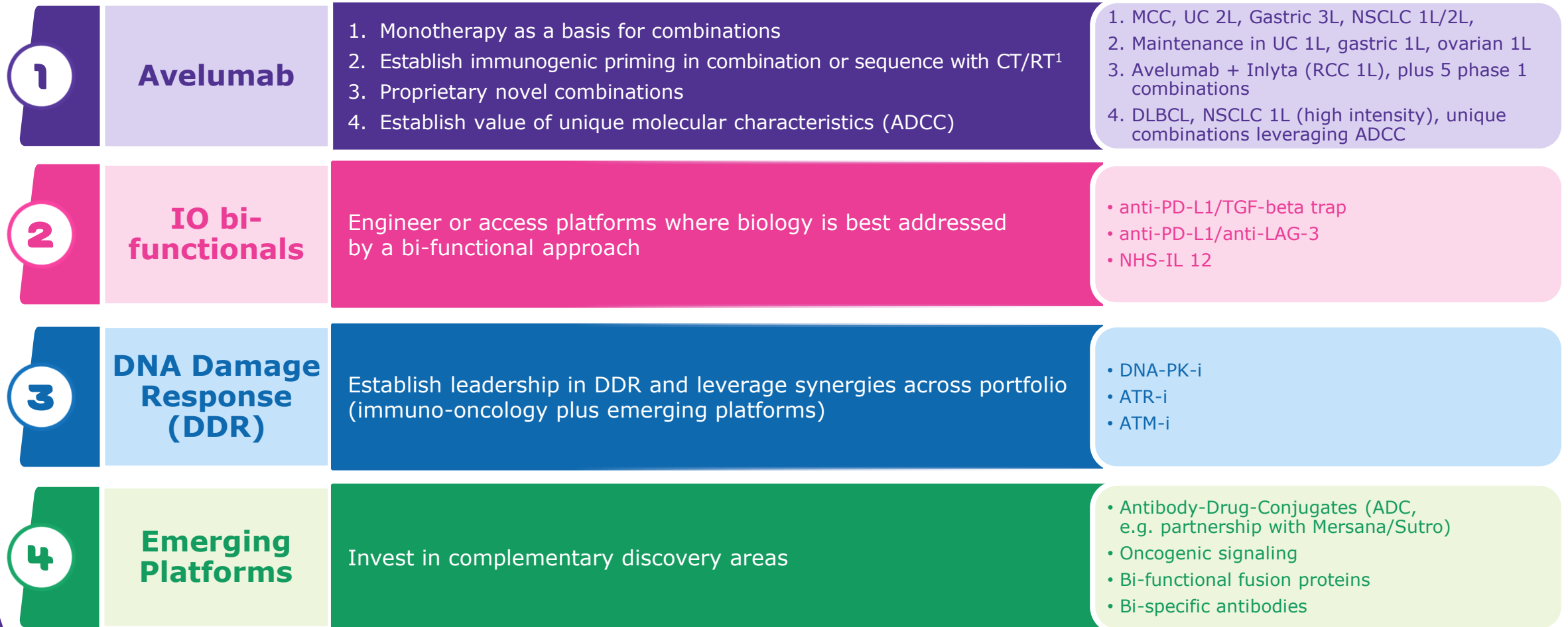
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DNA-Damage Response
Portfolio (DDR)

Oncology

Strategy anchored on four foundational pillars



External Innovation

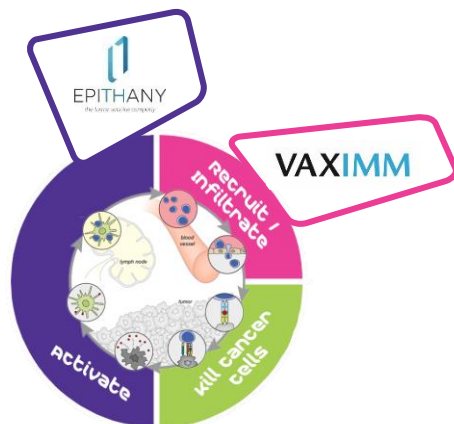
2017 deal activity aligned with strategic pillars

1

Clinical collaborations for avelumab combinations

expand across the immunity cycle

- **EpiThany:** EP-101 STEMVAC vaccine (breast cancer)
- **Vaximm:** Oral T-cell immunotherapy (glioblastoma, colorectal cancer)

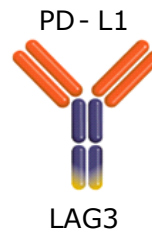


2



Leading bi-specific platform

- **Option deal**
- **Bi-specific antibodies** (promising lead asset **Anti-LAG3/ PD-L1**)
- FS118 shows superior activity pre-clinically (**expected in clinic 2018**)
- Potential in PDx-refractory setting
- Four additional mAb2 programs



3



strengthen DDR platform

- **Acquisition (license) deal**
- **Leadership** in DDR-i
- Combination of Vertex' Oncology and Merck's KGaA, Darmstadt, Germany DNA-PK inhibitor programs

Vertex

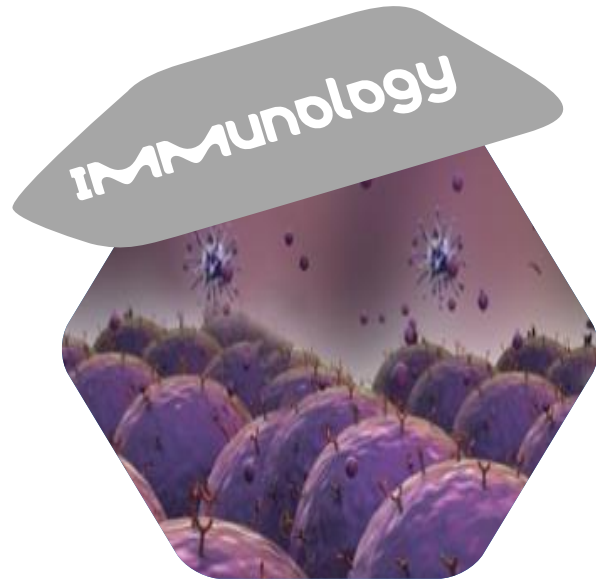
- Two **ATR-inhibitors**
- One **DNA-PK inhibitors**
- Two pre-clinical programs

MERCK KGaA, DARMSTADT, GERMANY

- DNA-PK inhibitor
- **ATM-inhibitor** (preclinical)

Agenda

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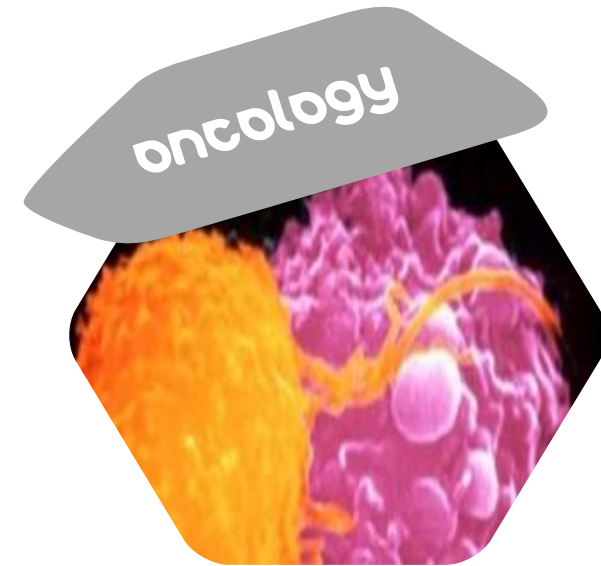
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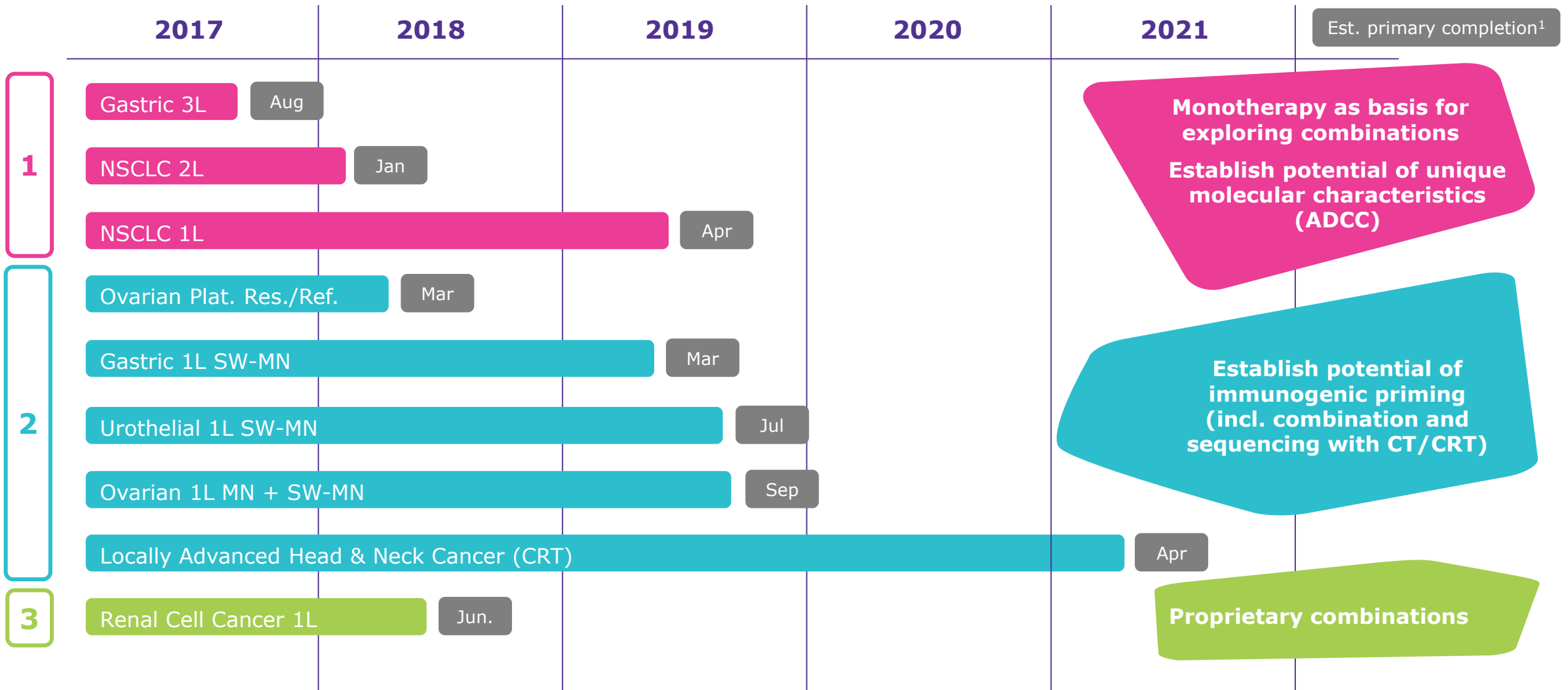


DNA-Damage Response
Portfolio (DDR)

1

Avelumab

Nine ongoing pivotal studies with differentiation potential



¹ Estimated primary completion date according to Clinicaltrials.gov.
Acronyms: CT: Chemotherapy | CRT: Chemoradiotherapy | Plat. Res./Ref.: Platinum Resistant/Refractory

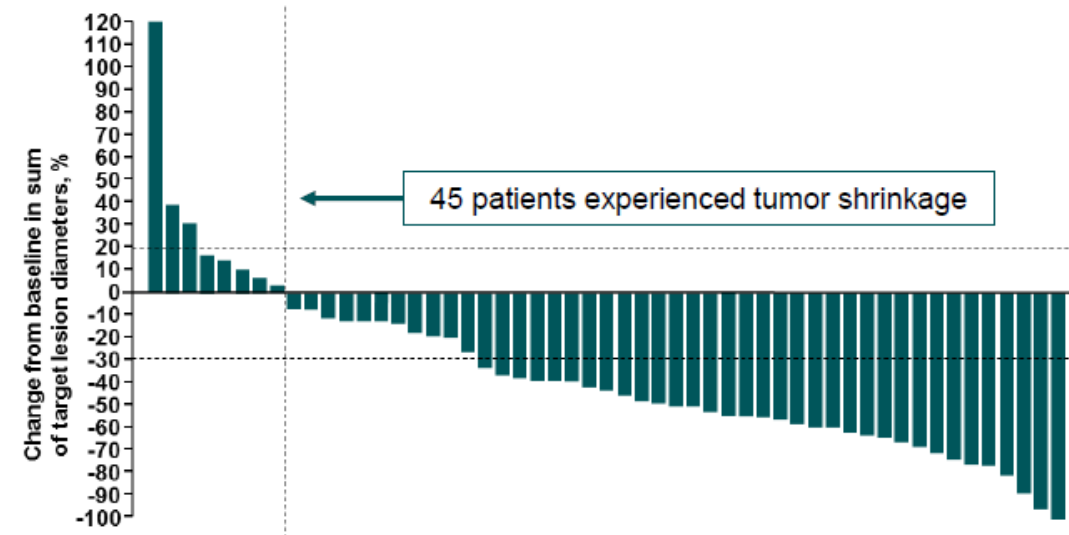
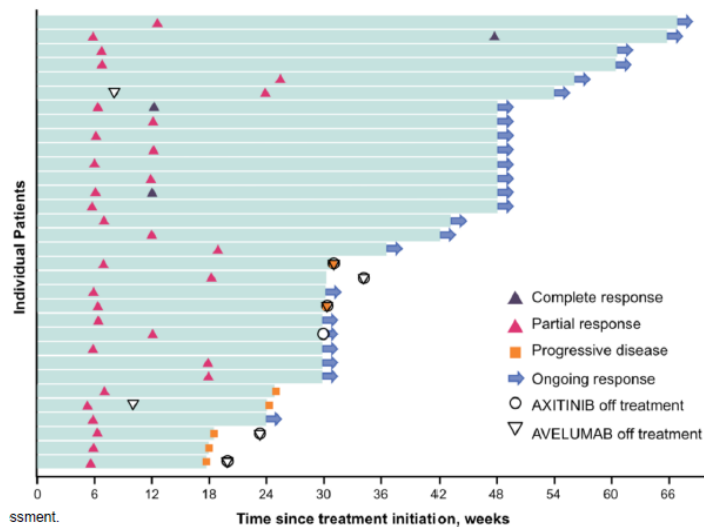


Avelumab

RCC 1L (phase Ib): Avelumab+Inlyta shows encouraging efficacy and safety¹

Confirmed best OR*, n (%)	Overall population (N=55)
Complete response	3 (5.5)
Partial response	29 (52.7)
Stable disease	11 (20.0)
Progressive disease	10 (18.2)
Nonevaluable [†]	2 (3.6)
ORR, % (95% CI)	58.2 (44.1–71.3)

- **Confirmed ORR of 58.2%:** beyond single-agent (Sutent ORR: 27.5%)
- **Safety profile manageable:** consistent with agents' monotherapy (Sutent: 77% Grade 3/4 AE)
- **Duration of response:** response at time of 1st tumor assessment in 20/32 patients (ongoing in 24/32 patients)
- **Tumor shrinkage:** 45 patients
- **Disease control:** in 78.2% of patients



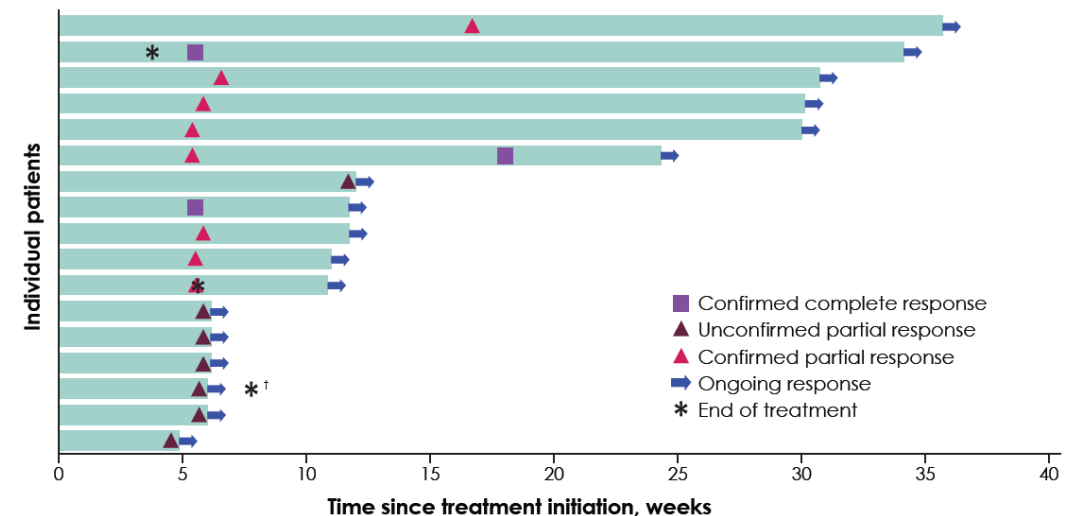


Avelumab

MCC 1L (phase II cohort): Avelumab demonstrates significant activity

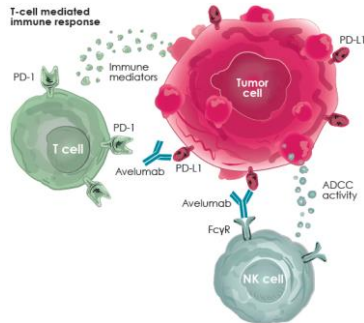
	Patients with ≥13 weeks of follow-up, confirmed* BOR (n=16)	Patients with ≥6 weeks of follow-up, unconfirmed BOR (n=25)
BOR, n (%)		
CR	3 (18.8)	3 (12.0)
PR	7 (43.8)	14 (56.0)
Stable disease	2 (12.5)	2 (8.0)
Progressive disease	3 (18.8)	5 (20.0)
Non-evaluable	1 (6.3) [†]	1 (4.0) [†]
ORR, %	62.5	68.0
95% CI	(35.4-84.8)	(46.5-85.1)

Adverse event (any grade ≥10% or any grade ≥3)	Any grade, n (%)	Grade ≥3, n (%)
Any TRAE	23 (79.3)	5 (17.2)
Fatigue	8 (27.6)	0
IRR*	7 (24.1)	1 (3.4)
Lipase increased	3 (10.3)	0
Elevated ALT	2 (6.9)	1 (3.4)
Gait disturbance	1 (3.4)	1 (3.4)
Elevated AST	1 (3.4)	1 (3.4)
Autoimmune nephritis	1 (3.4)	1 (3.4)
Cholangitis	1 (3.4)	1 (3.4)
Paraneoplastic syndrome	1 (3.4)	1 (3.4)



1 Avelumab NSCLC 1L: Assessing potential efficacy upside in mono-therapy¹

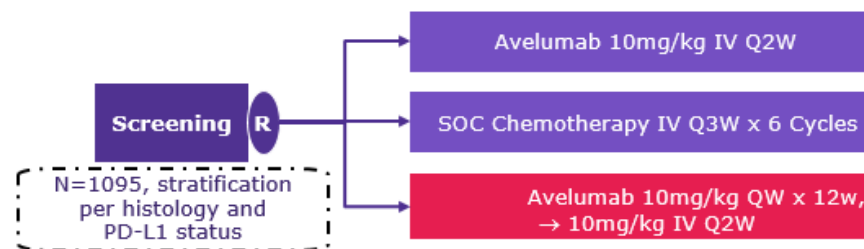
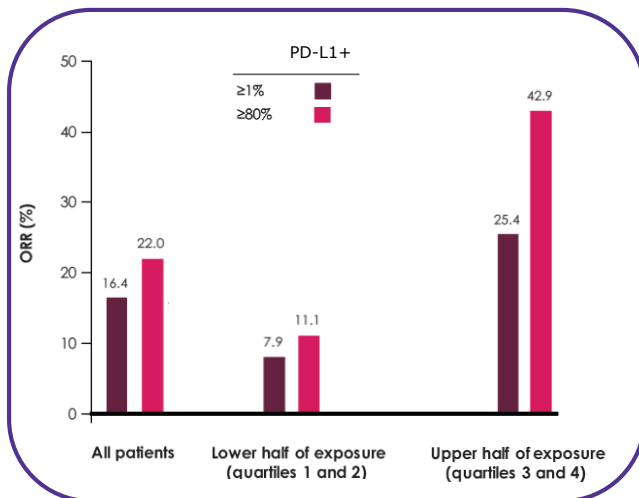
NSCLC 2L+: exposure response



NSCLC 1L: testing hypothesis of higher efficacy/intensity correlation

Hypothesis : higher drug intensity may result in greater efficacy (potentially driven by ADCC)

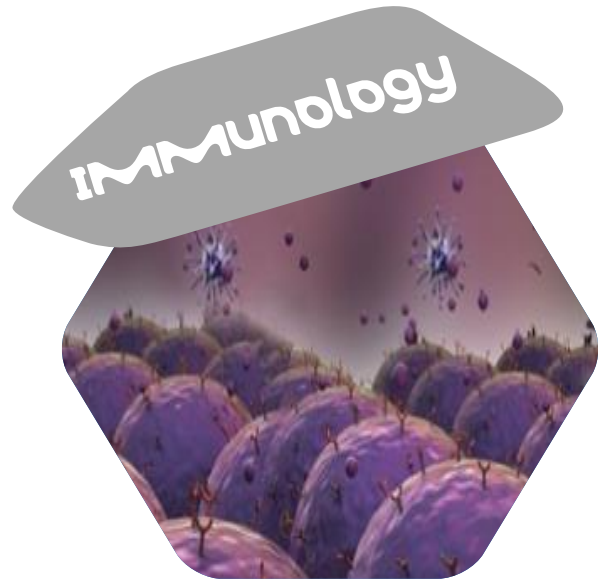
- Potential association between **higher ORR** and **higher avelumab exposure**
- ORR highest in patients with both higher avelumab **exposure** and tumors with higher levels of **PD-L1 expression**
- **NSCLC 1L phase III trial amended** to leverage high-intensity hypothesis (est. primary completion Apr 2019)



- **Primary endpoints:** PFS & OS @ high PD-L1-expression
- **Secondary endpoints:** PFS & OS @ moderate and low PD-L1-expression (BOR, DOR, Safety, QoL)
- **Hierarchical ordered hypothesis**

Agenda

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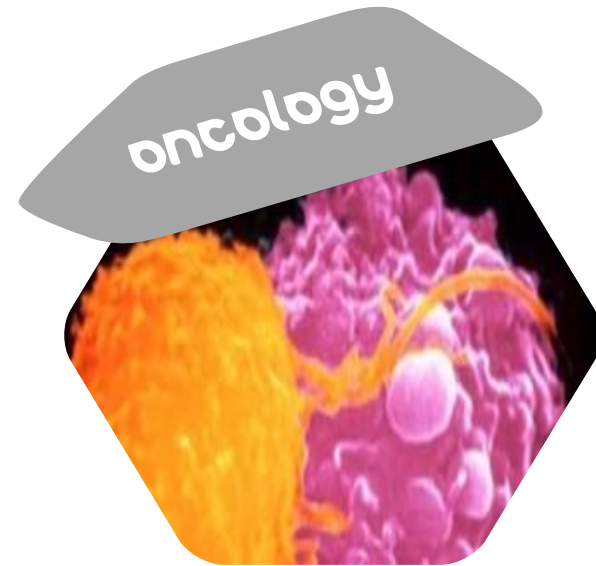
Cladribine Tablets

Evobrutinib



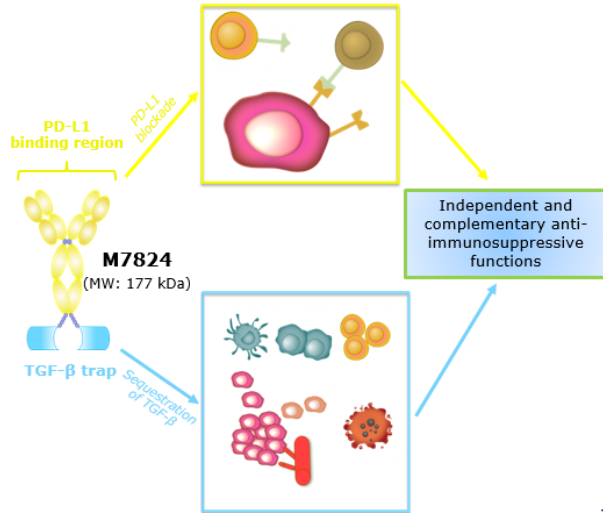
Avelumab

IO Bi-functionals



DNA-Damage Response Portfolio (DDR)

2 Anti-PD-L1/TGF- β trap Dose escalation completed, showing first signs of clinical activity¹



- **Innovative first-in-class bifunctional fusion protein** designed to simultaneously target two immune suppressive pathways (blocking PD-L1 and reducing TGF- β signaling)
- **Manageable safety profile** (patients with heavily pretreated advanced solid tumors)
- **Saturated peripheral PD-L1 and sequestered all released plasma TGF- β 1, - β 2, and - β 3¹**

Patients with metastatic or locally advanced solid tumors for which no standard effective therapy exists or standard therapy has failed (N = 19)

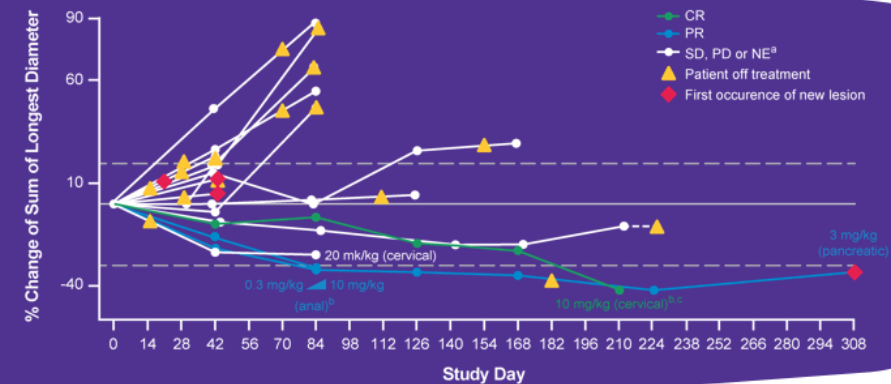
Dose Q2W, mg/kg	n
0.3 \blacktriangle 10	3
1	3
3	3
10	3
20	7

Primary endpoints

- TEAEs
- DLTs
- Treatment-related AEs

Secondary endpoints

- PK
- M7824 immunogenicity
- BOR



2 Anti-PD-L1/TGF-β trap Cohort data will enable decision per indication/category

Dose escalation completed¹

14 cohorts in recruitment

Defined criteria allow timely decision

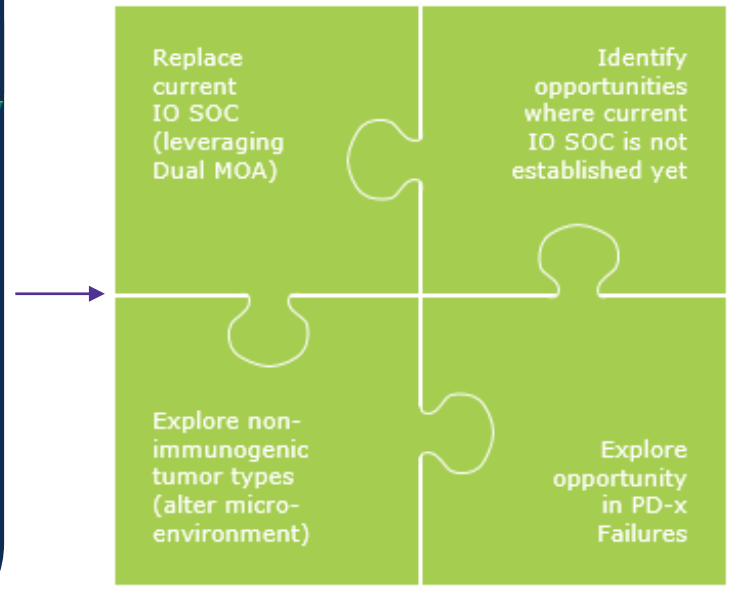
Preliminary results from a phase 1 trial of M7824 (MSB0011359C), a bifunctional fusion protein targeting PD-L1 and TGF-β, in advanced solid tumors

J. L. Gulley¹, C. R. Heery², J. Schlom¹, R. A. Madan³, L. Cao¹, E. Lamping⁴, J. L. Marte¹, L. M. Cordes⁵, O. Christensen⁶, C. Helwig⁷, J. Strauss¹

¹National Cancer Institute at the National Institutes of Health, Bethesda, MD; ²Laboratory of Tumor Immunology and Biology, National Cancer Institute at the National Institutes of Health, Bethesda, MD; ³National Cancer Institute, Bethesda, MD; ⁴Gastrointestinal Malignancies Branch, National Cancer Institute, NIH, Bethesda, MD; ⁵National Institutes of Health, Bethesda, MD; ⁶EMD Serono, Billerica, MA; ⁷Merck KGaA, Darmstadt, Germany

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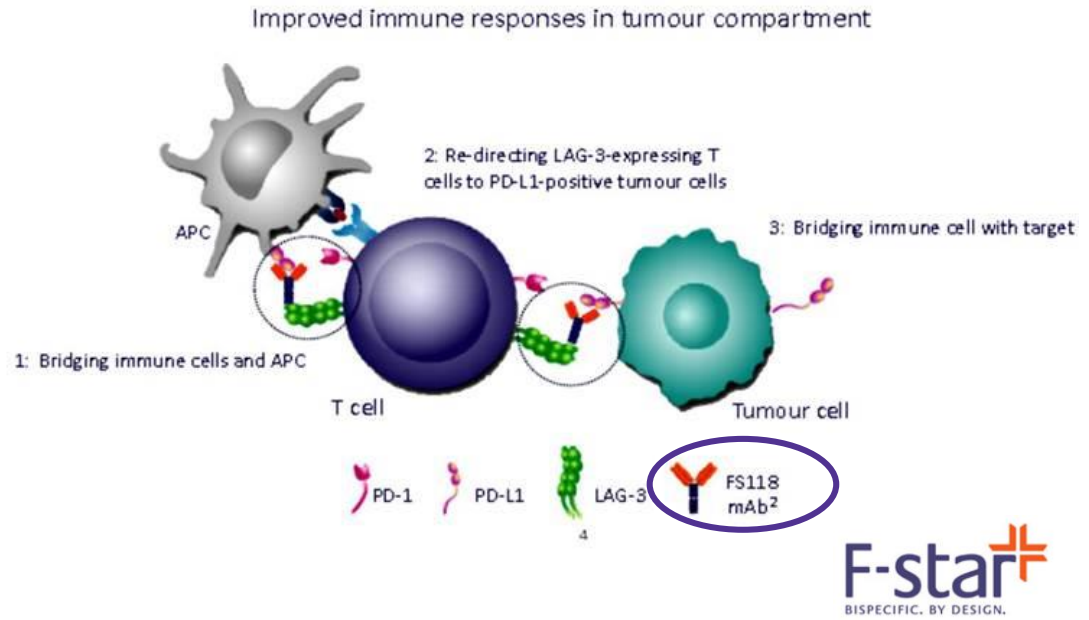
- **Ongoing confirmed CR** (cervical, 10 mg/kg)
- **Durable confirmed PR** (pancreatic, 3 mg/kg)^d
- **Unconfirmed PR** (anal, 0.3 mg/kg 10 mg/kg)
- **Near-PR** (cervical, 20 mg/kg)^e
- **Prolonged SD** (pancreatic, 3 mg/kg)^f
- **Prolonged SD** (carcinoid, 1 mg/kg)



- Expand cohort and/or explore single-arm path-to-registration
- Expand cohorts to confirm signal and/or follow with randomized comparative trial
- Explore biomarker driven pan-tumor opportunities
- De-prioritize cohort

2 Bi-specifics Combination of PD1/PD-L1 and LAG3 shows promise

Complementary mode of actions may enhance anti-tumor activity

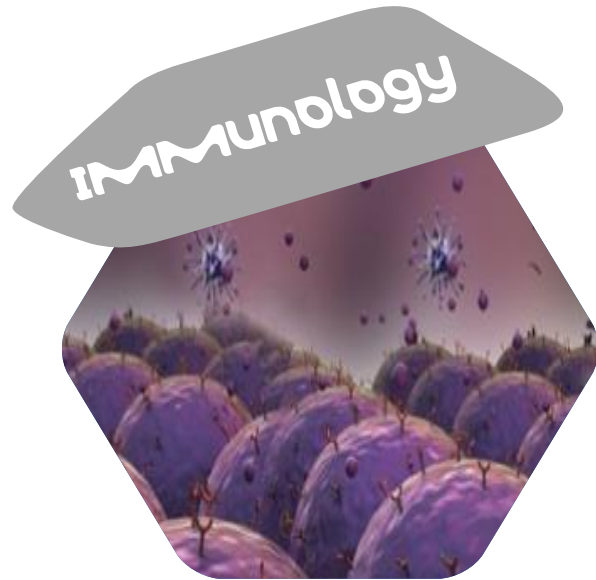


- **LAG3 is widely expressed on cytotoxic T cells** and tumor infiltrating lymphocytes (TILs)
- Functionally similar to other checkpoint inhibitors (e.g. CTLA-4 and PD-1)
- **Inhibition of suppressive LAG3 signaling** in T cells enhances T cell proliferation, cytokine production, **anti-tumor activity**
- Pre-clinical evidence of **synergistic efficacy of bi-specifics**: simultaneous blockade of LAG3 and PD1 synergistically enhance T-cell activity and anti- tumor immunity in mouse models

FS118 expected to enter clinic in 2018

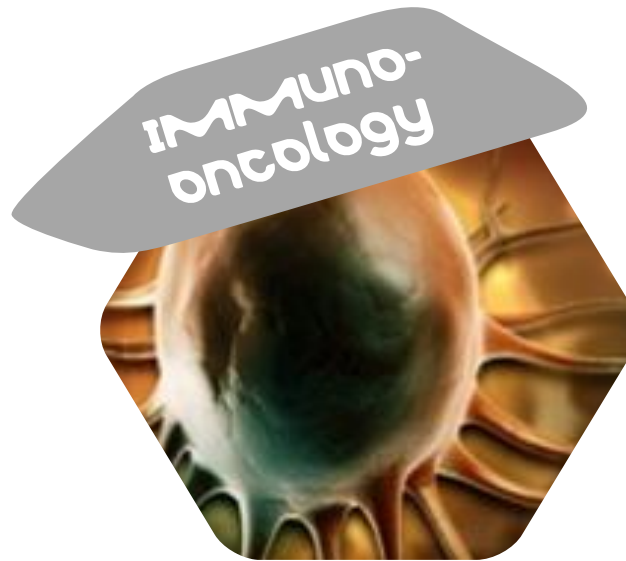
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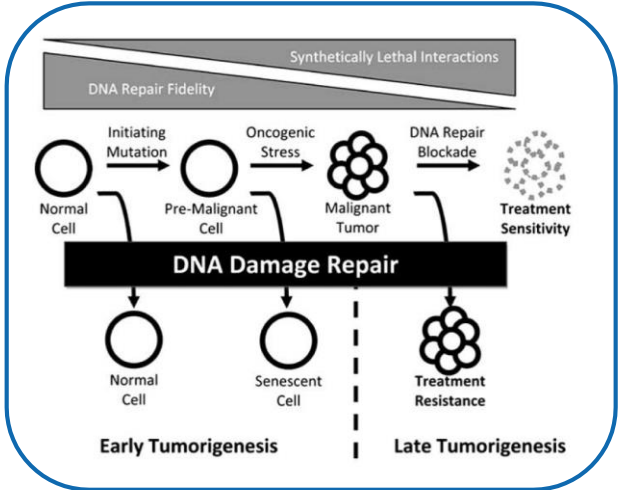
IO Bi-functionals



DNA-Damage Response
Portfolio (DDR)

3

DNA damage response (DDR) Complete portfolio supporting leadership in a potentially disruptive class



Genomic instability: a hallmark of late stage cancers¹

- DNA damage response (DDR) keeps genetic information intact
- In many cancers DDR pathways are defected, leading to greater dependency on remaining functional DDR pathways
- Preferentially inhibiting remaining DDR pathways can result in cancer cell death (“synthetic lethality”)

Type of damage:	Single-strand breaks (SSBs)	Double-strand breaks (DSBs)	Bulky adducts e.g. from platinum and UV	Nucleotide mutations, substitutions, deletions, insertions
Repair targets:	APE1 PARP	ATR ATM DNA-PK	ERCC1 XP proteins Polymerases	MLH, MSH, MTH1*, etc
Repair pathway:	Base Excision Repair	Homologous Recombination Repair Non-homologous End Joining	Nucleotide Excision Repair and Translesion Synthesis	Mismatch Repair
Damaging agent(s):	RTx Alkylating agents	RTx Topo I inhibitors Nucleoside analogue	UV light Platinum agents	Replication errors Alkylating agents
Rationale for targeting:	The most common lesion	The most cytotoxic lesion	Platinum potentiation but safety concern over UV sensitization	dNTP sanitation

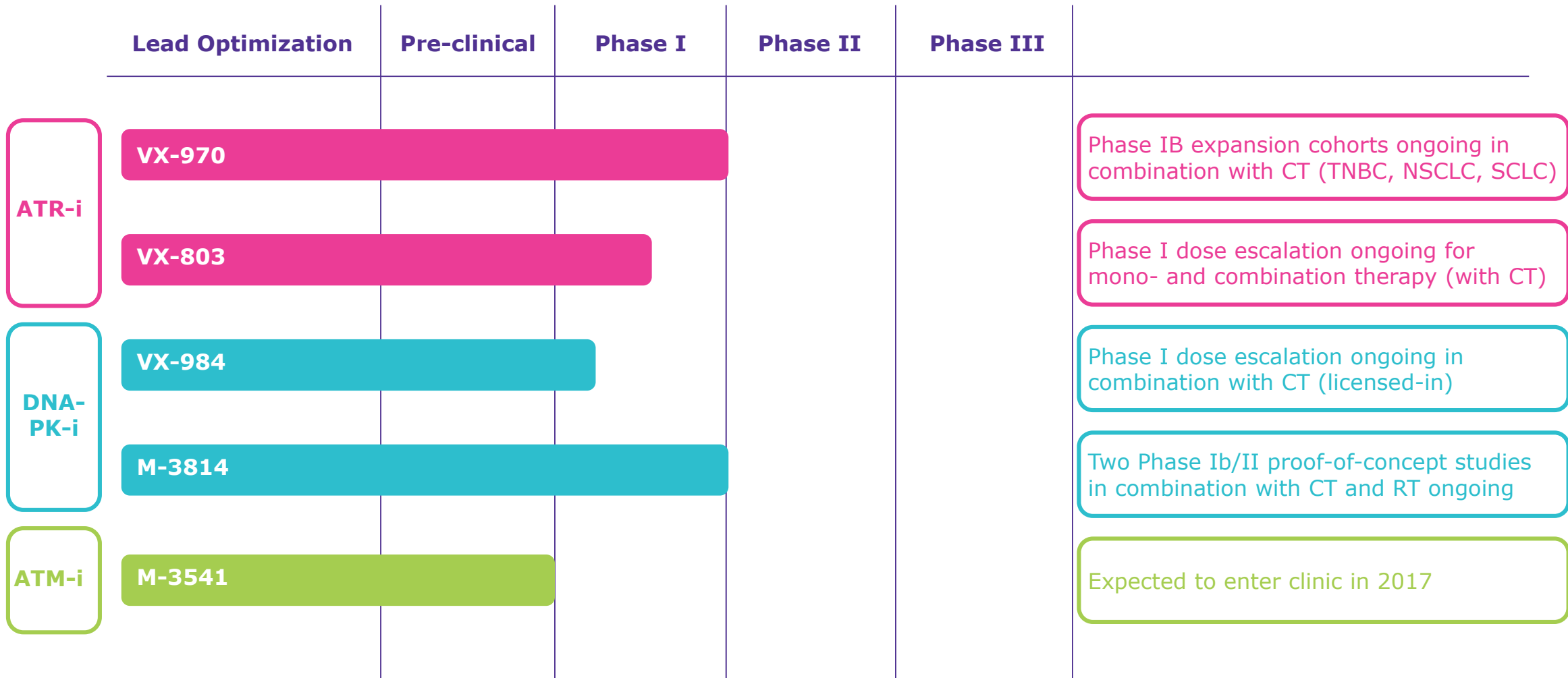
Amplifying cytotoxic effects of conventional and novel cancer treatments potentially bears combination potential

1. Inhibitor portfolio targets all three leading pathways of double stranded breaks – enabling unique synergies
2. ASCO 2017: leading DNA-PK-I (M3814) found safe and tolerable in a phase I study, with limited single-agent activity (20% of patients with stable disease for at least 18 weeks)²

¹ Sources: O’Connor, Molecular Cell, 2015 | Benjamin et al., Current Drug Targets, 2010, 11, 1336-1340
² “A multicenter phase I trial of the DNA-dependent protein kinase (DNA-PK) inhibitor M3814 in patients with solid tumors”, Mark van Bussel, ASCO 2017
 Acronyms: ATM: ataxia-telangiectasia mutated |ATR: ataxia telangiectasia and Rad3 | DNA-PK: DNA-dependent protein kinase |

3

DNA damage response (DDR) Clinical program targets all three DDR pathways, in mono- and combination



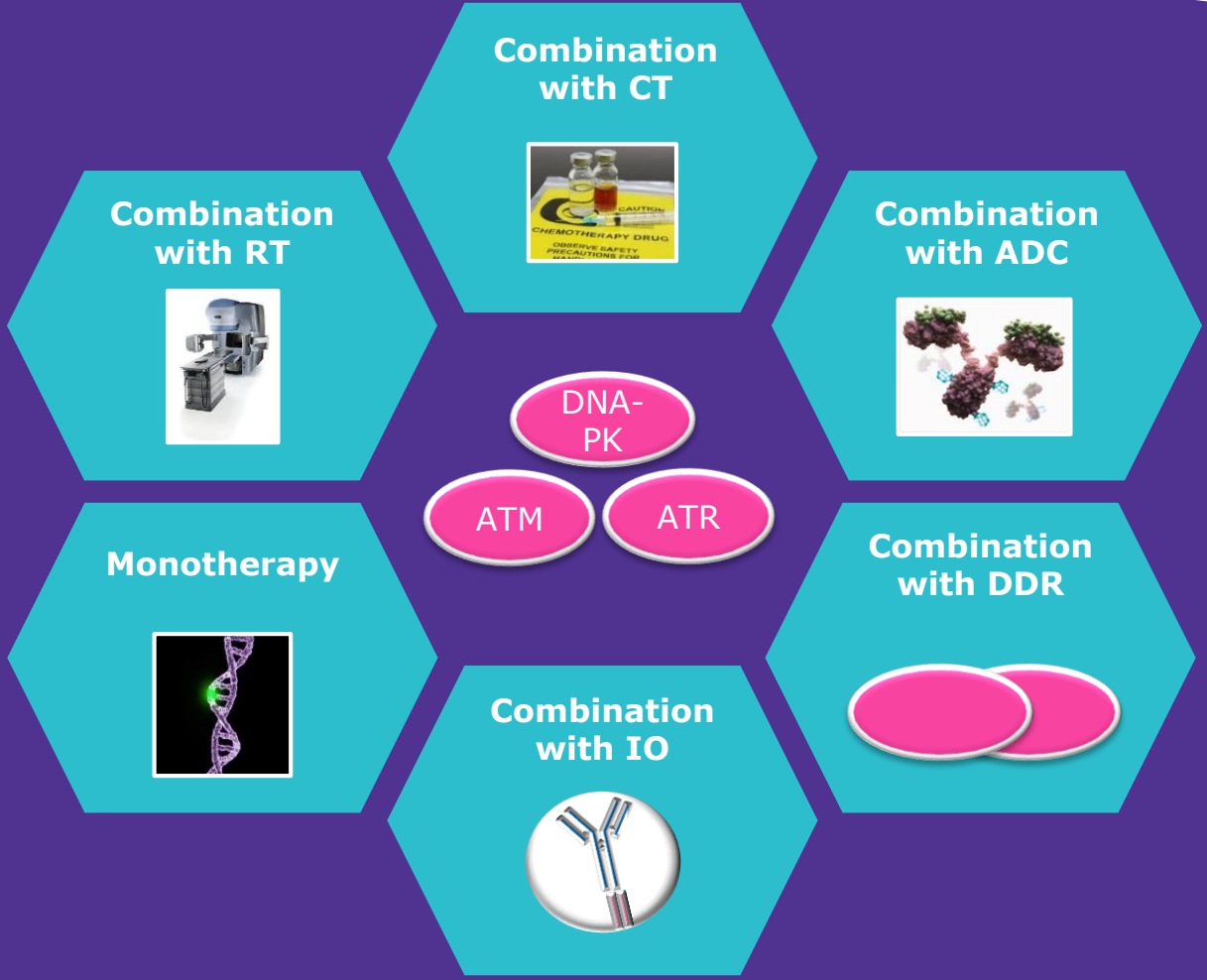
3

DNA damage response (DDR) Broad combination potential across multiple mechanisms

At least **50%** of all cancer patients receive some type of **RADIATION** therapy (NCI 2016)

At least **70%** of all cancer patients receive some type of **CHEMOTHERAPY** (NCI 2016)

Significant share of patients to be treated with **CHECKPOINT INHIBITORS**



Pipeline

Early stage strengthened – enabling late stage optionality across all TAs¹

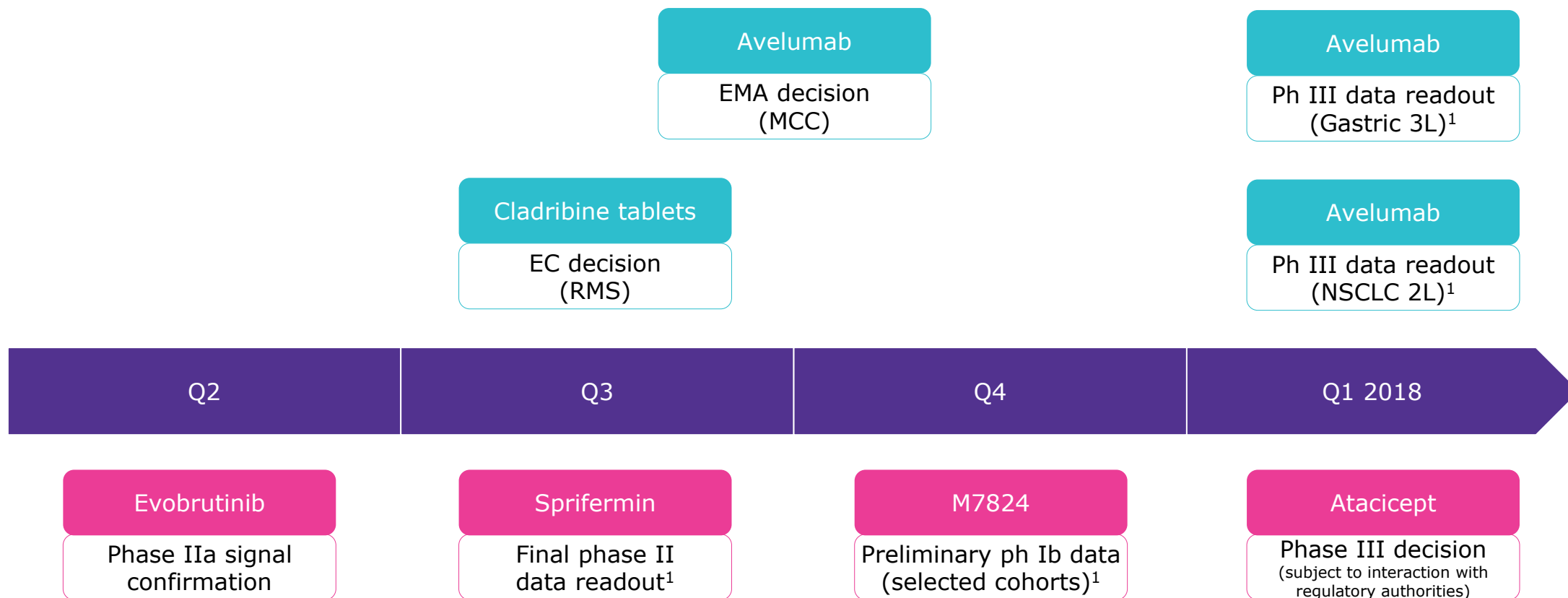
	Phase I	Phase II	Phase III	Filing	
Immunology	<div style="background-color: #00A0C0; color: white; padding: 5px; margin-bottom: 5px;">Anti-IL-17 A/F Psoriasis</div>	<div style="background-color: #4B4B8B; color: white; padding: 5px; margin-bottom: 5px;">Atacept SLE</div> <div style="background-color: #E91E63; color: white; padding: 5px; margin-bottom: 5px;">BTK inhibitor SLE</div> <div style="background-color: #90C040; color: white; padding: 5px; margin-bottom: 5px;">Atacept IgA Nephropathy</div> <div style="background-color: #90C040; color: white; padding: 5px; margin-bottom: 5px;">BTK inhibitor RA</div> <div style="background-color: #4B4B8B; color: white; padding: 5px; margin-bottom: 5px;">sprifermin Osteoarthritis</div> <div style="background-color: #90C040; color: white; padding: 5px; margin-bottom: 5px;">BTK inhibitor MS</div> <div style="background-color: #A9A9A9; color: white; padding: 5px; margin-bottom: 5px;">ATX-MS-1467 MS</div> <div style="background-color: #90C040; color: white; padding: 5px;">Abituzumab SSc-ILD</div>			<div style="background-color: #E91E63; color: white; padding: 5px;">Cladribine Tablets RMS (EU)</div>
Oncology	<div style="background-color: #4B4B8B; color: white; padding: 5px; margin-bottom: 5px;">p70S6K & Akt-i Solid tumors</div> <div style="background-color: #90C040; color: white; padding: 5px; margin-bottom: 5px;">BTK inhibitor Hem. malignancies</div> <div style="background-color: #A9A9A9; color: white; padding: 5px; margin-bottom: 5px;">BRAF-I (Beigene) Solid tumors</div> <div style="background-color: #4B4B8B; color: white; padding: 5px; margin-bottom: 5px;">DNA-PK-i Solid tumors</div> <div style="background-color: #90C040; color: white; padding: 5px; margin-bottom: 5px;">DNA-PK-I (VX-984) Solid tumors</div> <div style="background-color: #90C040; color: white; padding: 5px; margin-bottom: 5px;">ATR-i⁷ (VX-970) Solid tumors</div> <div style="background-color: #90C040; color: white; padding: 5px;">ATR-I (VX-803) Solid tumors</div>	<div style="background-color: #4B4B8B; color: white; padding: 5px; margin-bottom: 5px;">tepotinib NSCLC</div> <div style="background-color: #4B4B8B; color: white; padding: 5px;">Tepotinib HCC</div>			
Immuno-Oncology	<div style="background-color: #4B4B8B; color: white; padding: 5px; margin-bottom: 5px;">anti-PD-L1/TGF-β trap Solid tumors</div> <div style="background-color: #90C040; color: white; padding: 5px; margin-bottom: 5px;">Avelumab Hem. malignancies</div> <div style="background-color: #4B4B8B; color: white; padding: 5px; margin-bottom: 5px;">Avelumab Solid tumors</div> <div style="background-color: #90C040; color: white; padding: 5px; margin-bottom: 5px;">Avelumab comb.** DLBCL</div> <div style="background-color: #4B4B8B; color: white; padding: 5px; margin-bottom: 5px;">Avelumab+41BB/OX40 Solid tumors</div> <div style="background-color: #90C040; color: white; padding: 5px; margin-bottom: 5px;">Avelumab + NHS IL 12 Solid tumors</div> <div style="background-color: #90C040; color: white; padding: 5px;">Avelumab (mono/combo) Various ISTs</div>	<div style="background-color: #E91E63; color: white; padding: 5px; margin-bottom: 5px;">Avelumab MCC 1L</div>	<div style="background-color: #4B4B8B; color: white; padding: 5px; margin-bottom: 5px;">Avelumab NSCLC 1L¹</div> <div style="background-color: #4B4B8B; color: white; padding: 5px; margin-bottom: 5px;">Avelumab NSCLC 2L²</div> <div style="background-color: #4B4B8B; color: white; padding: 5px; margin-bottom: 5px;">Avelumab Gastric 1L MN¹</div> <div style="background-color: #4B4B8B; color: white; padding: 5px; margin-bottom: 5px;">Avelumab Gastric 3L³</div> <div style="background-color: #4B4B8B; color: white; padding: 5px;">Avelumab Ovarian plat. res./ref</div> <div style="background-color: #4B4B8B; color: white; padding: 5px; margin-bottom: 5px;">Avelumab RCC 1L¹</div> <div style="background-color: #4B4B8B; color: white; padding: 5px; margin-bottom: 5px;">Avelumab Urothelial 1L MN¹</div> <div style="background-color: #E91E63; color: white; padding: 5px; margin-bottom: 5px;">Avelumab LA SCCHN</div> <div style="background-color: #E91E63; color: white; padding: 5px;">Avelumab Ovarian 1L (Chemo)¹</div>	<div style="background-color: #E91E63; color: white; padding: 5px;">Avelumab⁵ Merkel cell (EU) </div>	
Biosimilars			<div style="background-color: #A9A9A9; color: white; padding: 5px;">Adalimumab biosimilar Chr. plaque Psoriasis</div>		

Externalized
 New in pipeline
 Moved to next phase
 Maintained position
 R Registered (US)
 Terminated²

¹ Since R&D Update call on June 20, 2016 | ² Either terminated (ATX, BRAF-i) or divested (Biosimilars) | Acronyms: SLE = systemic lupus erythematosus, RRMS = relapse remitting multiple sclerosis, NSCLC = non-small cell lung cancer, HCC = hepatocellular carcinoma, STS = soft-tissue carcinoma, MCC = Merkel cell carcinoma, RA = rheumatoid arthritis, SCCHN = squamous cell cancer of the head and neck, SSC-ILD: Systemic sclerosis with interstitial lung disease | DLBCL: Diffuse Large B-cell Lymphoma

Outlook

2 potential launches, 4 pivotal catalysts and major value inflection points



Outlook

Healthcare is well set for future growth

Stable existing
business



Base business delivering solidly with stable outlook

R&D pipeline
optionality



High quality assets across all three areas continuously complemented with short- and longer term optionalities

Innovative
partnerships



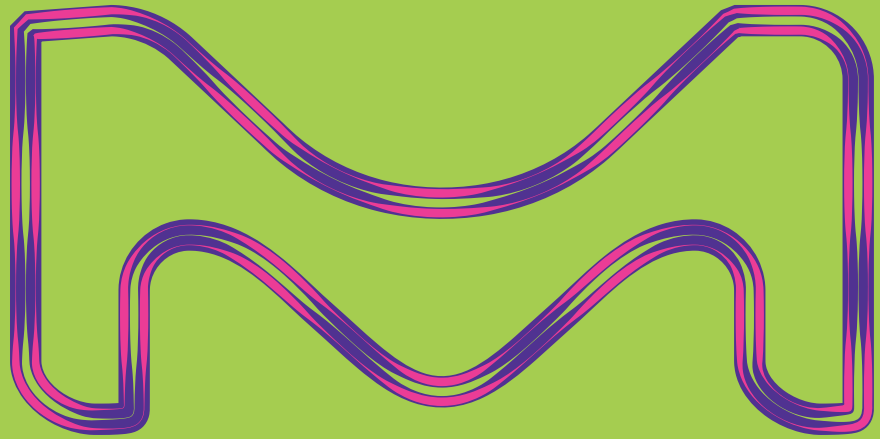
Joint investments and innovative deals models to maximize potential of assets and maintain focus

Disciplined
execution



Systematic pipeline review and timely decision making ensure efficient resource and budget allocation





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