

abbvie

# AbbVie Immunology Strategy and Long-Term Outlook

December 14, 2020

# AbbVie Leadership Team Participants

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Richard A. Gonzalez  
Chairman of the Board and Chief  
Executive Officer



Michael E. Severino, M.D.  
Vice Chairman and President



Robert A. Michael  
Executive Vice President,  
Chief Financial Officer



Jeffrey R. Stewart  
Executive Vice President,  
Chief Commercial Officer



Elaine K. Sorg  
Senior Vice President and  
President of US Commercial Operations

# Forward-Looking Statements and Other Notices

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Some statements in this presentation are, or may be considered, forward-looking statements for purposes of the Private Securities Litigation Reform Act of 1995. The words "believe," "expect," "anticipate," "project" and similar expressions, among others, generally identify forward-looking statements. AbbVie cautions that these forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those indicated in the forward-looking statements. Such risks and uncertainties include, but are not limited to, the failure to realize the expected benefits of AbbVie's acquisition of Allergan or to promptly and effectively integrate Allergan's business, challenges to intellectual property, competition from other products, difficulties inherent in the research and development process, adverse litigation or government action, and changes to laws and regulations applicable to our industry. Additional information about the economic, competitive, governmental, technological and other factors that may affect AbbVie's operations is set forth in Item 1A, "Risk Factors," of AbbVie's 2019 Annual Report on Form 10-K, which has been filed with the Securities and Exchange Commission, as updated by its Quarterly Reports on Form 10-Q and in other documents that AbbVie subsequently files with the Securities and Exchange Commission that update, supplement or supersede such information. AbbVie undertakes no obligation to release publicly any revisions to forward-looking statements as a result of subsequent events or developments, except as required by law.

Today's discussions and presentation are intended for the investor community only; materials are not intended to promote the products referenced herein or otherwise influence healthcare prescribing decisions.

# Agenda

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AbbVie Immunology Overview  
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Rheumatology  
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.....  
Dermatology  
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Gastroenterology  
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Immunology R&D Strategy  
.....

# AbbVie is the Market Leader in Immunology

Best-in-Class Medicines and Innovative Pipeline Position AbbVie for Sustained Leadership

Our Vision is to Eliminate the Burden of Disease for Those Touched by Immune-Mediated Diseases with Significant Unmet Need



Delivery of **best-in-class** products across a **broad set of diseases**



Development of **robust, integrated strategies** leading to unprecedented **adoption, adherence and value**



**Undisputed leader** in Immunology market and well-positioned for **sustained leadership over next decade**



New Immunology products expected to contribute **greater than \$15B in 2025\***, significantly above prior guidance

\*Risk-adjusted sales estimate

# Humira is the Global Market Leader in Immunology



**#1** Immunology drug with expected sales approaching \$20 billion in 2020



**23** Years of clinical data



**16** Approved indications globally

HUMIRA in  
**16 indications** across  
Rheum, Derm, and Gastro

RA	JIA
AS	PsA
Uveitis	Ped. Uveitis
PsO	Ped. PsO
HS	Adol. HS
CD	Ped. CD
UC	Ped UC
Int. Behcet's	Pyoderma Gangrenosum

# Humira Expected to Continue to Provide Growth Up to the U.S. LOE

## U.S. Humira

**\$16B**

Expected 2020 Revenue  
Representing Growth of 8%



Continued Volume Growth  
Expected in 2021 and 2022

**8**

Biosimilars Expected to  
Launch in 2023

**LOE**

Expect Steep Erosion in Year 1,  
Moderating in Subsequent Years

## International Humira

**\$3.7B**

Expected 2020 Revenue

**-45%**

Sales Erosion in Biosimilar Markets  
in First Year Facing Competition

**4**

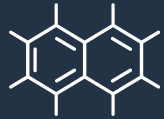
Biosimilars  
Launched in 2018

**\$1.5B**

Remaining Revenue Expected to Face  
Biosimilar Competition in 2021+

# AbbVie's Strategy to Advance Industry-Leading Science and Remain the Market Leader in Immunology

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**Thoughtfully designed clinical programs** to establish a robust body of data to support asset differentiation across a broad set of indications and patient populations



**Speed to market** to quickly advance Rinvoq and Skyrizi to ensure a timely cadence of launches



**Shift focus and investment** to Skyrizi and Rinvoq in core diseases as approved






**Innovate** to advance new MOAs, novel therapies and predictive biomarkers in core as well as new disease areas



# Best-In-Class Portfolio with Rinvoq, Skyrizi, and Humira

## Focus and Investment Shifting to New Assets as Approved

### Marketed and Late-Stage Immunology Portfolio

	RHEUMATOLOGY			DERMATOLOGY			GASTROENTEROLOGY	
	RA	PsA	AS / NR-axSpA	PsO	AD	HS	CD	UC
 <b>HUMIRA</b> <sup>®</sup> adalimumab	★	★	★	★		★	★	★
 <b>RINVOQ</b> <sup>™</sup> upadacitinib <small>50mg tablets</small>	★	☆	☆		☆	Ph2	Ph3	Ph3
 <b>Skyrizi</b> <sup>™</sup> risankizumab-rzaa <small>75mg/0.63mL Injection</small>		Ph3		★		Ph2	Ph3	Ph3

★ Currently Approved    ☆ Under Regulatory Review

**Accelerated development expected to result in the commercialization of Skyrizi and Rinvoq across all Humira’s major indications plus atopic dermatitis by 2022. This indication expansion would occur in less than half of Humira’s development timeline.**

This slide contains investigational indications not yet approved by regulatory authorities. RA = rheumatoid arthritis, PsA = psoriatic arthritis, AS = ankylosing spondylitis, NR-AxSpA = non-radiographic axial spondyloarthritis, PsO = psoriasis, AD = atopic dermatitis, HS = hidradenitis suppurativa, CD = Crohn’s disease, UC = ulcerative disease

# Key Success Factors Driving Sustained Leadership in Immunology

## Highly Differentiated Profiles



- H2H Superiority vs. Humira (RA)
- H2H Superiority vs. Orencia (RA)
- H2H Superiority vs. Dupixent (AD)



- H2H Superiority vs. Humira (PsO)
- H2H Superiority vs. Stelara (PsO)
- H2H Superiority vs. Cosentyx (PsO)

- Rinvog and Skyrizi provide compelling benefit/risk profiles in approved indications

## Exceptional Execution

- Overwhelming share-of-voice leveraging AbbVie's exceptional Commercial, Medical Affairs and Market Access organizations in more than 170 countries



- Best-in-class physician and patient support programs providing the knowledge, skills and tools to make informed treatment decisions

- Industry leading direct-to-consumer activation

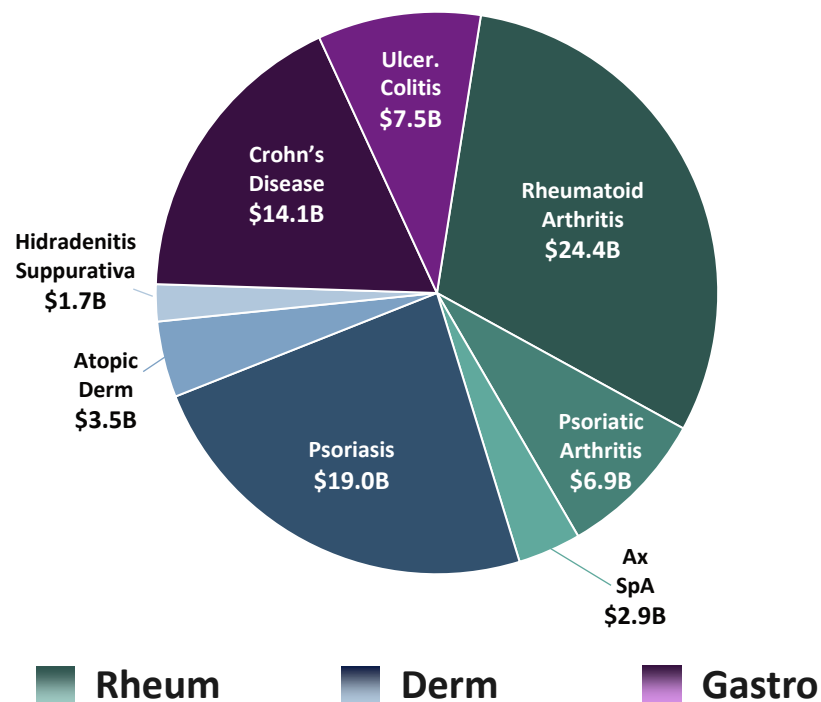
Rinvog has not been approved in atopic dermatitis (AD) and its safety and efficacy in this indication has not been evaluated by regulatory agencies.

# Global Immunology Market

More than 25 Million Treated Patients; Representing ~\$80 Billion Market Value

**Despite Advancements Over the Past Decade, There is Still Enormous Remaining Unmet Need in Immune-Mediated Diseases**

### 2020 Global Immunology Market



**High residual need exists in AbbVie's core diseases**

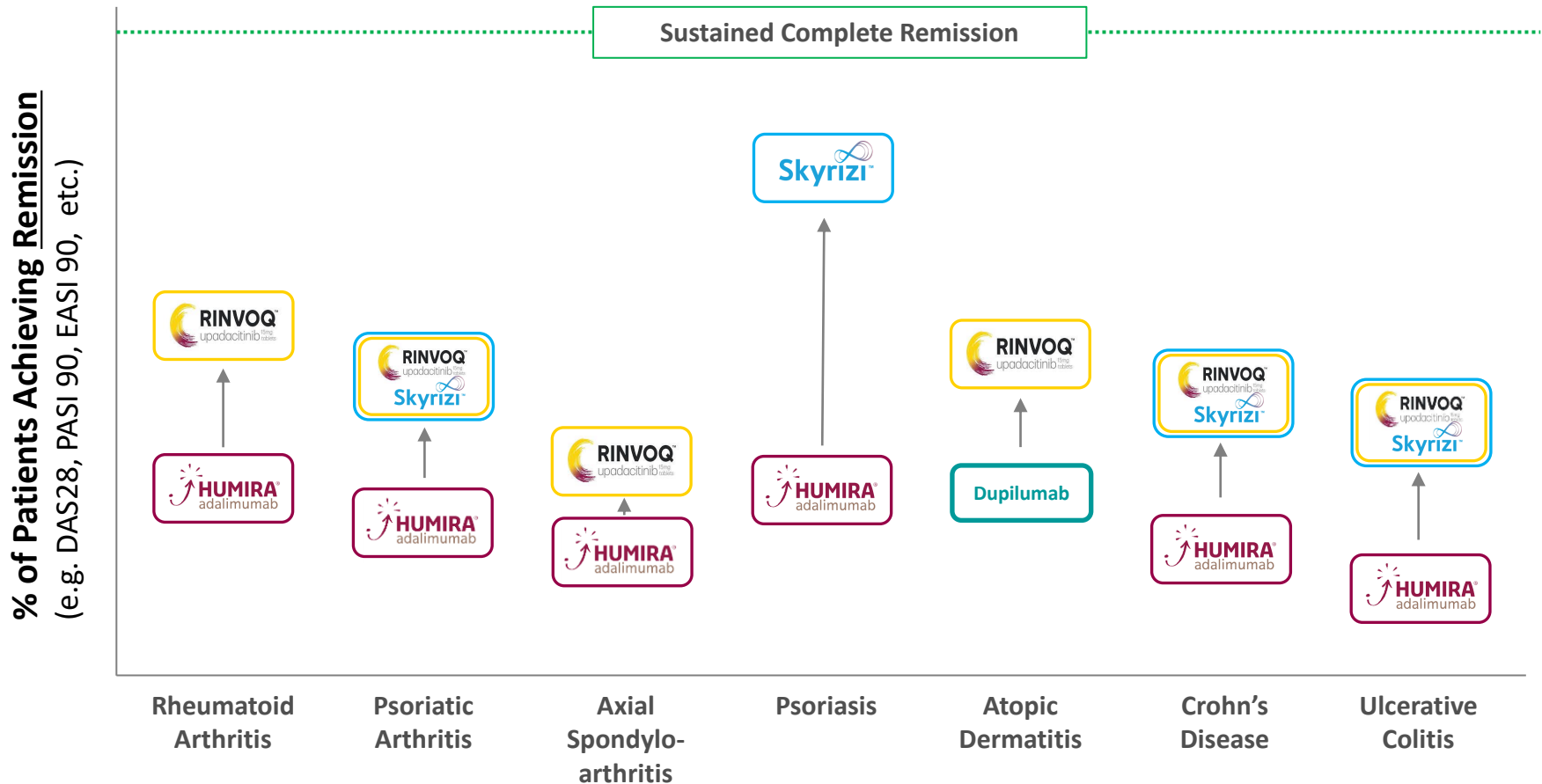
**Low TIM-penetration and under-development in specific markets**

**Substantial opportunity also exists to address new diseases**

Note: TIM (Target Immuno Modulators) including biologics and oral small molecule therapies. Immunology market refers to indications where AbbVie has drugs approved or in development. Sources: IQVIA, Accredo, Evaluate Pharma, Symphony Health Patient Data, AbbVie estimates.

# High Residual Need Still Exists in Core Diseases

Advancing Science Provides a Greater Opportunity for Improved Outcomes



**Despite Our Successes, There is Still Enormous Remaining Unmet Need in Immune-Mediated Diseases**

Rinvoq has not been approved in PsA, AS, axial SpA, AD, CD or UC and Skyrizi has not been approved in PsA, CD or UC, and their safety and efficacy in these indications have not been evaluated by regulatory agencies. This slide is intended to qualitatively depict the potential opportunity for improved efficacy in select immune-mediated diseases. Remission refers to a state of low or no disease activity, as defined by each indication's respective clinical trial endpoints assessing disease activity. Aspects of this slide are aspirational in nature.

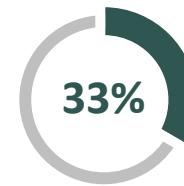
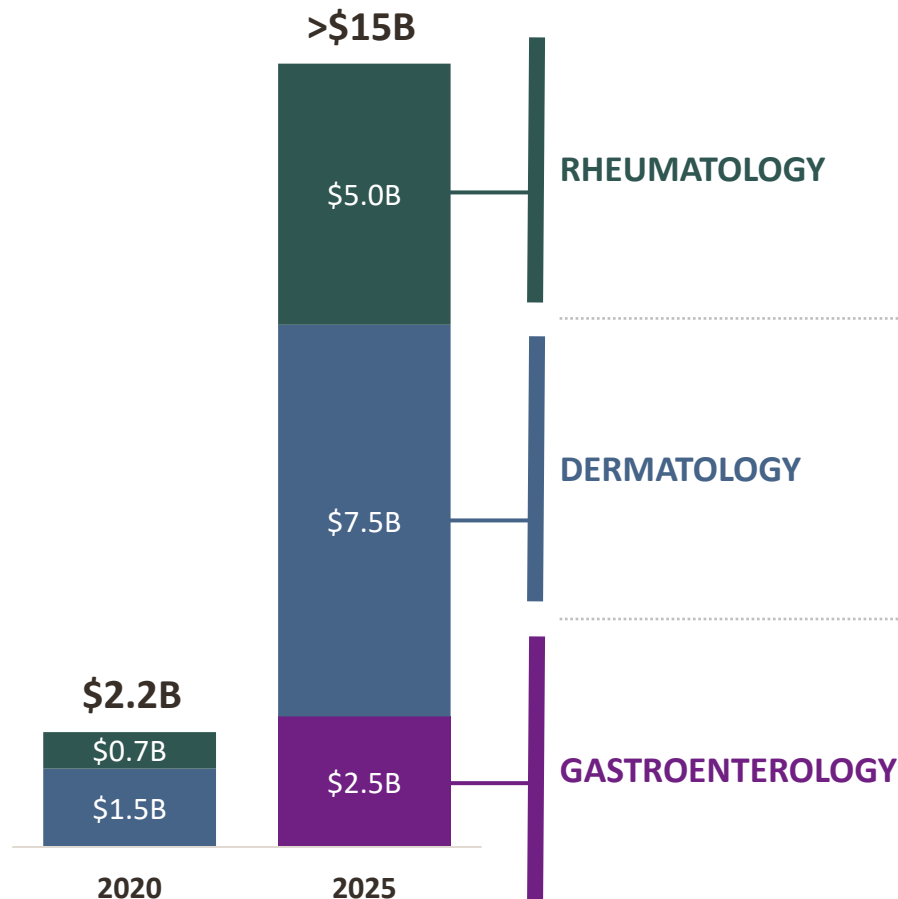
# Rinvoq and Skyrizi Represent Tremendous Long-Term Value

## Rinvoq and Skyrizi Risk-Adjusted Sales

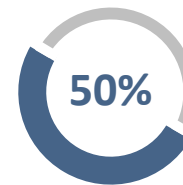
## Immunology Segment

## 2025 Sales Contribution

## Major Drivers

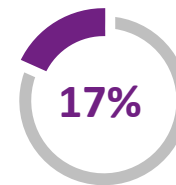


**Rinvoq's** best-in-class profile expected to continue to drive market share in **RA**, with anticipated launches in 2021 for **PsA** and **AS** further strengthening Rinvoq's position in Rheumatology



**Rinvoq's** high level of skin clearance and rapid itch relief, with convenient oral administration, expected to drive significant growth in the fast-developing **atopic dermatitis** market upon approval

**Skyrizi's** best-in-category efficacy, durable skin clearance and safety profile will continue to drive utilization and market share in **psoriasis** patients



**Ulcerative colitis** and **Crohn's disease** remain disease areas of high unmet need and both **Rinvoq** and **Skyrizi** study results have demonstrated high clinical remission and endoscopic improvement

Competitive profiles in both indications have potential to support rapid adoption in the **IBD** category

Rinvoq has not been approved in PsA, AS, AD, CD or UC and Skyrizi has not been approved in CD or UC, and their safety/efficacy in these indications haven't been evaluated by regulatory agencies.

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RHEUMATOLOGY

# Rheumatology at a Glance

Represents a Key Area of Focus for AbbVie Immunology Franchise

## Market

**\$34B**

Estimated 2020 Global  
Rheumatology Market Value

**+8%**

2020 U.S. Rheumatology  
Market TRx Growth

**40%**

U.S. TIM-Penetration  
in Rheumatology

**20%**

EU5 TIM-Penetration  
in Rheumatology

## AbbVie

**26%**

Humira + Rinvoq  
U.S. RA **Total** Market Share

**32%**

Humira + Rinvoq  
U.S. RA **In-Play** Patient Share

**58%**

Rheumatology Portion  
of AbbVie Immunology Sales

**8**

Rheumatology Programs  
in Development

Note: Rheumatology includes RA, PsA and Axial SpA.

Sources: IQVIA, Accredo, Decision Resources Group, Symphony Health Patient Data, AbbVie estimates.

# Rheumatoid Arthritis Market

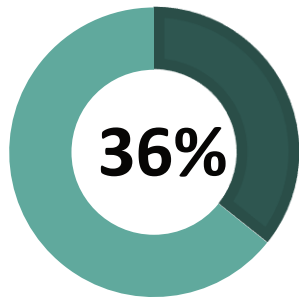
## 2020 Market Summary

**\$24B**

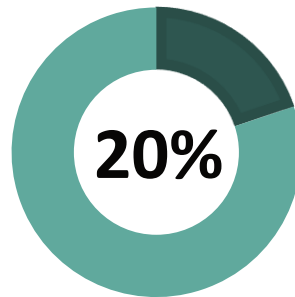
Estimated Global  
Market Value

**+7%**

U.S. TRx  
Growth



U.S.  
TIM-Penetration



EU5  
TIM-Penetration

## Key Market Trends



Expect continued growth in drug-treatment rates over the next 5 years given widespread awareness of disease state



Increasing share and uptake of agents outside of the anti-TNF class, with efficacious oral JAK inhibitors being most promising



Growing TIM-experienced population and increased likelihood of physicians switching to different MOAs post anti-TNF failure

Sources: IQVIA, Accredo, Decision Resources Group, Symphony Health Patient Data, AbbVie estimates.

Note: TIM-penetration refers to TIM-treated patients as a percent of the total drug-treated patient population. AbbVie estimates approximately 793,000 TIM-treated RA patients in the U.S. and approximately 345,000 TIM-treated RA patients in EU5. EU5 refers to UK, Germany, Spain, Italy and France.



# Rinvoq in Rheumatoid Arthritis

Delivering Remission and Broad Efficacy to RA patients with Convenient Oral Dosing

## Greater Remission VS. PBO+MTX & ADA+MTX

- Rinvoq + MTX is the first therapy to demonstrate significantly greater remission rates vs. placebo + MTX, adalimumab + MTX and abatacept + MTX

## Consistent Efficacy

- Rinvoq demonstrated consistent rates of remission, and significant inhibition of structural joint damage, with and without MTX

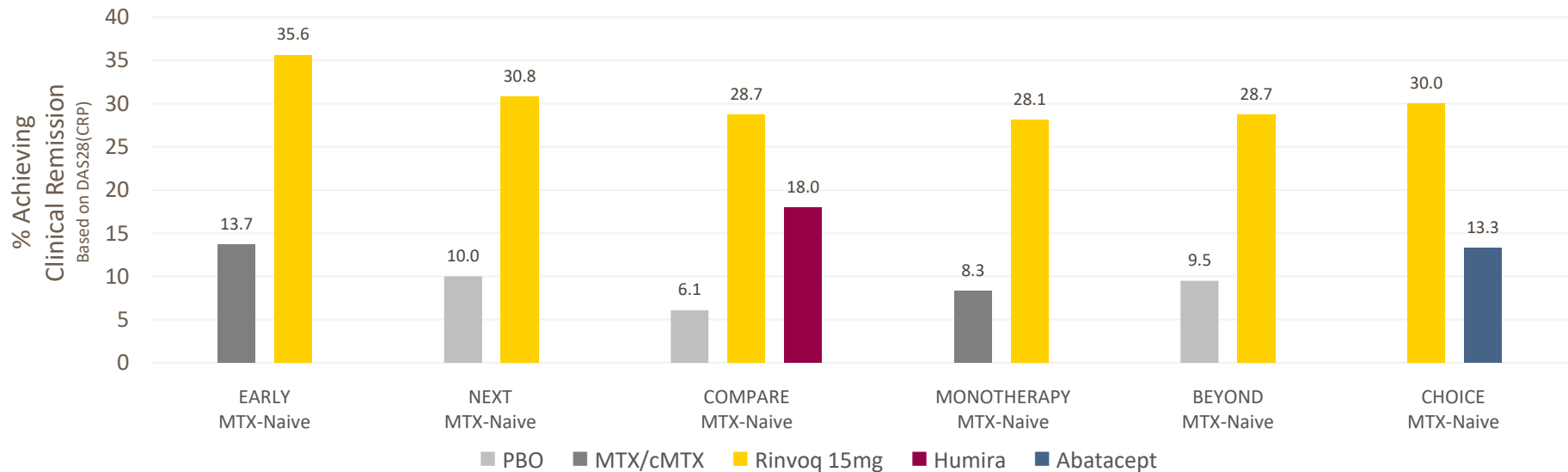
## Well-Characterized Safety Profile

- Rinvoq's safety profile has been established across 6 robust clinical trials in RA involving more than 4,000 patients and representing more than 10,000 patient-years of exposure

## Exceptional Access and Patient Support

- Industry-leading support programs for patients and caregivers

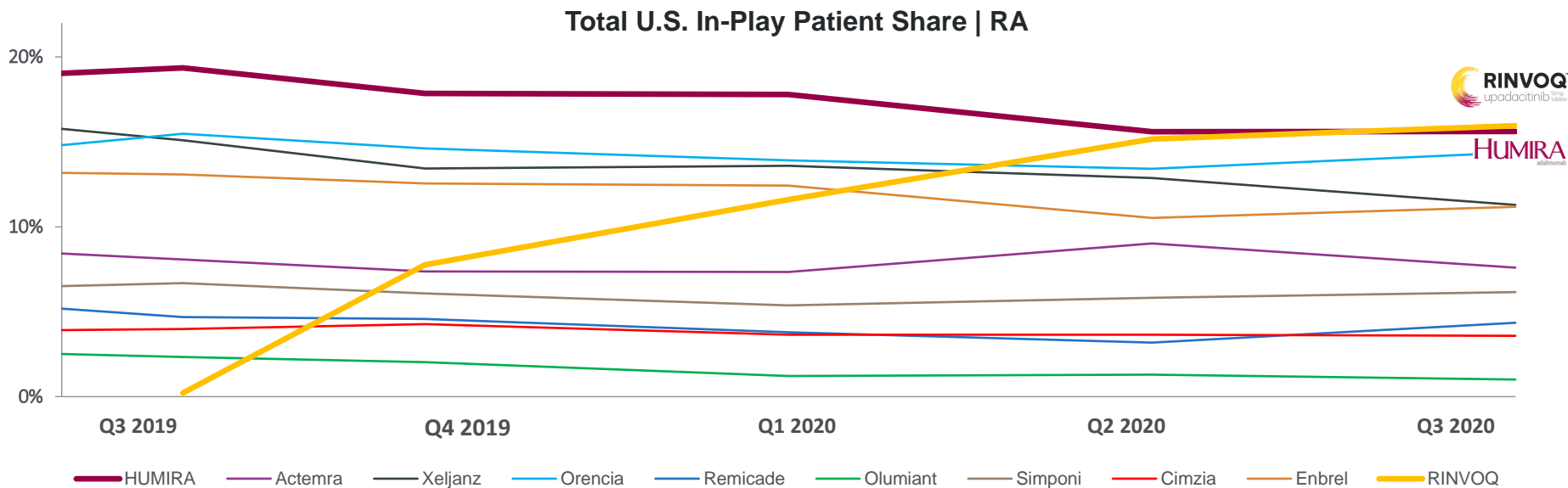
## Consistent remission rates at 3 months with Rinvoq across patient populations with or without MTX



Note: PBO = Placebo, MTX = Methotrexate, ADA = Adalimumab

# Rinvoq Launch in RA is Exceeding Expectations

Fastest Launch Uptake in RA, Achieving U.S. In-Play Leadership Within First Year



**16% U.S. In-Play Patient Share**



**4% U.S. Total Market Share**



**>95% Commercial Access**



**\$4B**  
Expected 2025  
WW RA Sales

Source: IQVIA, Accredio, Decision Resources Group and internal AbbVie estimates  
 Note: In-Play patient share represents both new and switching patients

# Psoriatic Arthritis Market

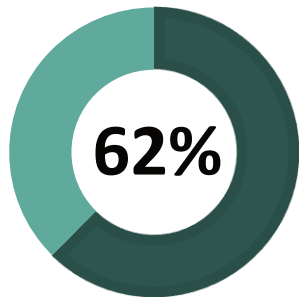
## 2020 Market Summary

**\$7B**

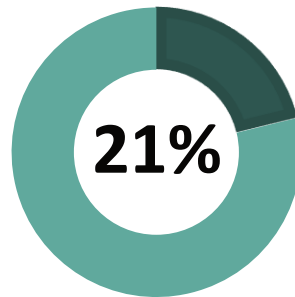
Estimated Global  
Market Value

**+12%**

U.S. TRx  
Growth



U.S.  
TIM-Penetration



EU5  
TIM-Penetration

## Key Market Trends



Emerging PsA therapies expected to provide sustained joint efficacy, effectiveness across key manifestations, higher skin clearance and higher disease control



Advanced therapies will drive continued TRx market growth, especially in the faster growing biologic-experienced segment



Higher TIM-penetration rates as patients move to novel therapies with improved efficacy, availability of oral options

Sources: IQVIA, Accredo, Decision Resources Group, Symphony Health Patient Data, AbbVie estimates.

Note: TIM-penetration refers to TIM-treated patients as a percent of the total drug-treated patient population. AbbVie estimates approximately 257,000 TIM-treated PsA patients in the U.S. and approximately 113,000 TIM-treated PsA patients in EU5. EU5 refers to UK, Germany, Spain, Italy and France.

# Key Results of Rinvoq Psoriatic Arthritis Clinical Program

## Rapid and Durable Joint Efficacy

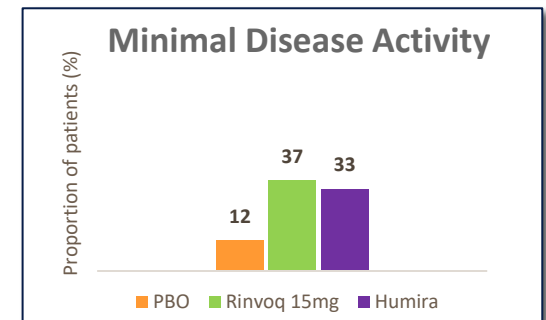
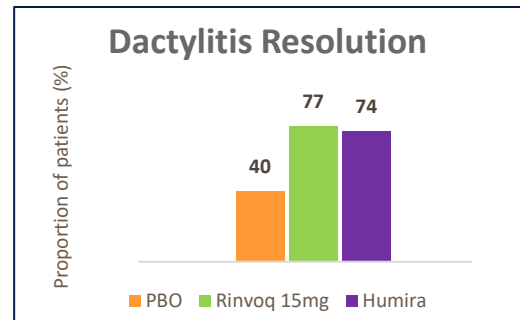
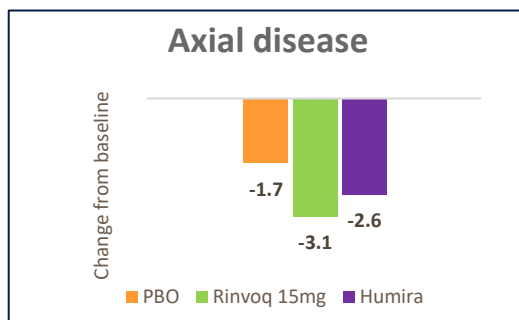
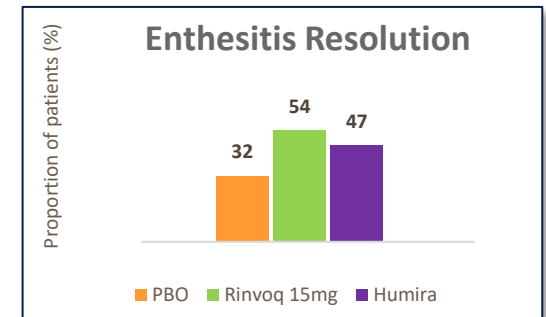
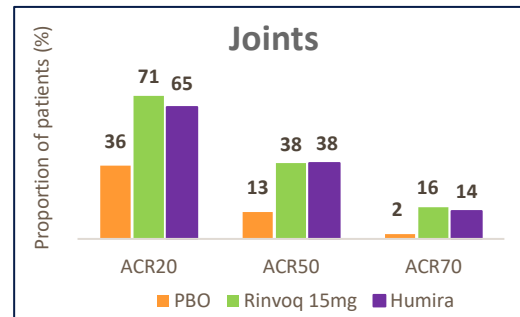
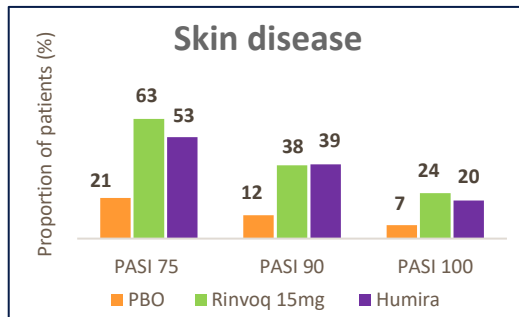
- Strong levels of response in both joint and skin endpoints, even in heavily pretreated, biologic-refractory patients

## Efficacy Across Key PsA Manifestations

- Minimal disease activity (with/without csDMARD)
- Resolution of enthesitis and dactylitis
- Skin clearance

## Well-Studied Safety Profile in Rheumatology Indications

- Well-studied safety profile in PsA across 1828 patients, 2504 Patient Years
- Side-by-side vs Humira and Placebo
- Established safety profile across 8 registrational trials in RA, PsA and AS



Rinvoq has not been approved in PsA and its safety and efficacy in this indication has not been evaluated by regulatory agencies. Data from SELECT-PsA 1 clinical study.

# Axial Spondyloarthritis Market

## Ankylosing Spondylitis and Non-Radiographic Axial Spondyloarthritis

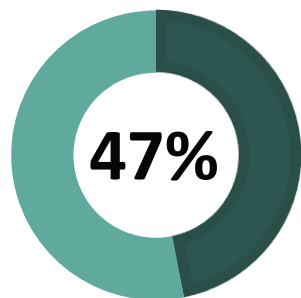
### 2020 Market Summary

**\$3B**

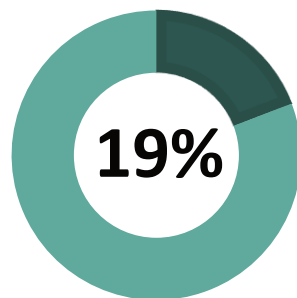
Estimated Global  
Market Value

**+10%**

U.S. TRx  
Growth



U.S.  
TIM-Penetration



EU5  
TIM-Penetration

### Key Market Trends



Significant advancements in therapeutic options, including IL-17s and JAK inhibitors, is supporting awareness and increasing diagnosis of the eligible patient population



High enthusiasm for oral options in younger patient demographic



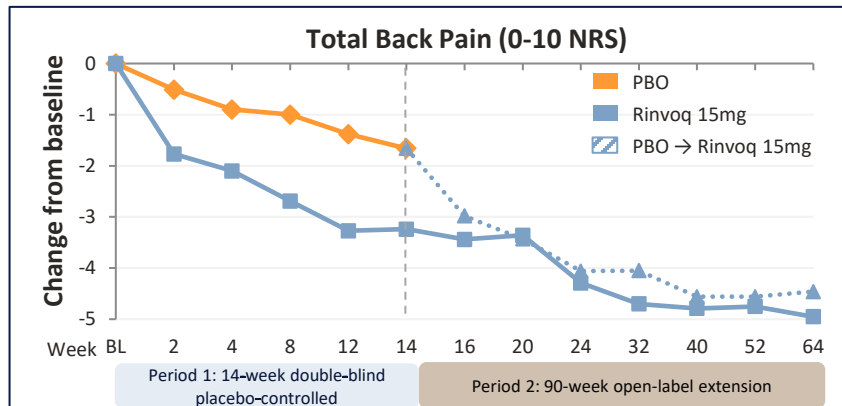
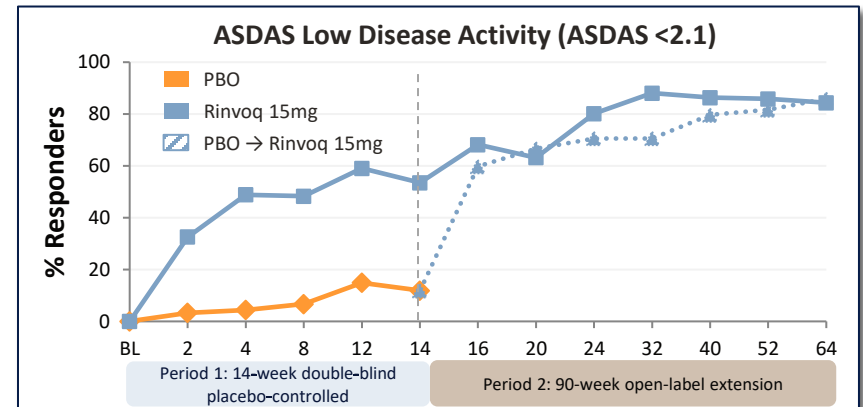
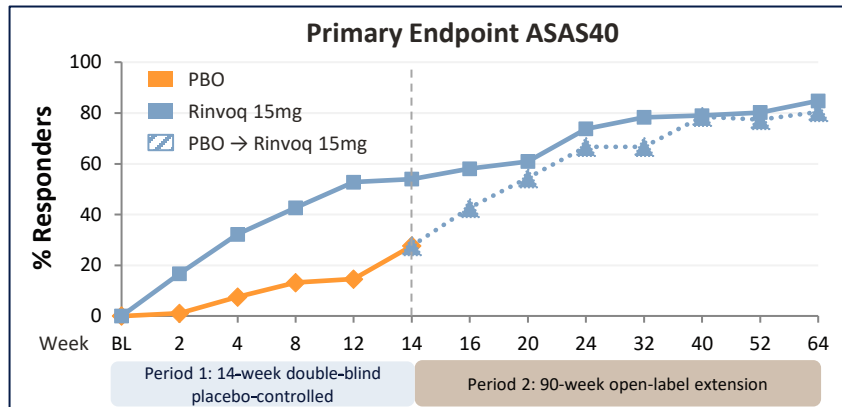
Growing acceptance of non-radiographic axial SpA supports a larger pool of treated patients

Sources: IQVIA, Accredo, Decision Resources Group, Symphony Health Patient Data, AbbVie estimates.

Note: TIM-penetration refers to TIM-treated patients as a percent of the total drug-treated patient population. U.S. market data refer to ankylosing spondylitis (AS) indication only; EU5 and other international market data refer axial spondyloarthritis (axial SpA) indication (including AS and non-radiographic axial SpA). AbbVie estimates approximately 77,000 TIM-treated AS patients in the U.S. and approximately 138,000 TIM-treated axial SpA patients in EU5. EU5 refers to UK, Germany, Spain, Italy and France.

# Key Result from Rinvoq Ankylosing Spondylitis Phase 2/3 Study

## Rinvoq Provided Sustained Disease Control in Ankylosing Spondylitis Across Stringent Endpoints and Rapid and Durable Reduction in Pain



No new safety findings observed in ankylosing spondylitis studies



Consistent safety profile established in 8 registrational trials across AS, RA, and PsA involving > 6,000 patients



SELECT-AXIS 1 trial enabled 2-year acceleration for filing of Rinvoq in ankylosing spondylitis

Rinvoq has not been approved in ankylosing spondylitis and its safety and efficacy in this indication has not been evaluated by regulatory agencies. Data from SELECT-AXIS 1 clinical study

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DERMATOLOGY

# Dermatology at a Glance

Significant Growth Potential with Skyrizi's Momentum in Psoriasis and Rinvoq's Anticipated Near-term Expansion into Atopic Dermatitis

## Market

**\$24B**

Estimated 2020 Global Dermatology Market Value

**+14%**

U.S. Dermatology Market TRx Growth in 2020

**8%**

U.S. TIM-Penetration in Dermatology

**2%**

EU5 TIM-Penetration in Dermatology

## AbbVie

**37%**

Humira + Skyrizi  
U.S. Psoriasis  
**Total Market Share**

**45%**

Humira + Skyrizi  
U.S. Psoriasis  
**In-Play Patient Share**

**16%**

Dermatology Portion of AbbVie Immunology Sales

**4**

Dermatology Programs in Development

Note: Dermatology includes PsO and AD.

Sources: IQVIA, Accredo, Decision Resources Group, Symphony Health Patient Data, AbbVie estimates.



# Psoriasis Market

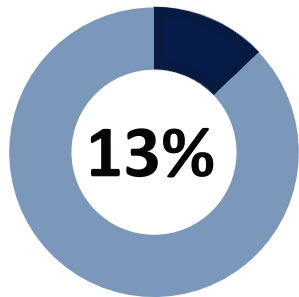
## 2020 Market Summary

**\$19B**

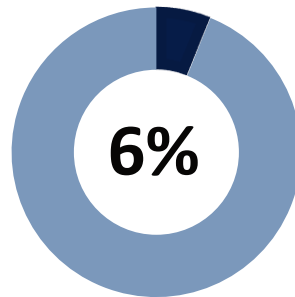
Estimated Global  
Market Value

**+13%**

U.S. TRx  
Growth



U.S.  
TIM-Penetration



EU5  
TIM-Penetration

## Key Market Trends



High efficacy agents including IL23, IL17, novel orals expected to significantly expand TIM-penetration



More moderate patients entering the market with the introduction of newer options with high rates of durable complete skin clearance, improved tolerability and more convenient dosing and administration



Higher patient adherence and persistency to advanced biologics with improved product profiles

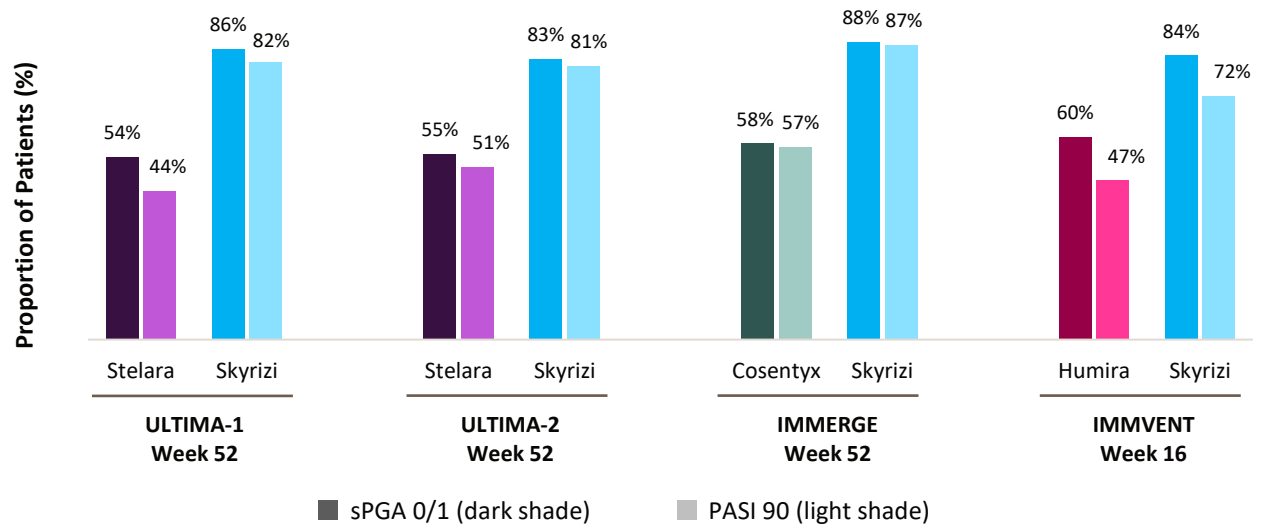
Sources: IQVIA, Accredo, Decision Resources Group, Symphony Health Patient Data, AbbVie estimates.

Note: TIM-penetration refers to TIM-treated patients as a percent of the total drug-treated patient population. AbbVie estimates approximately 425,000 TIM-treated Ps patients in the U.S. and approximately 171,000 TIM-treated Ps patients in EU5. EU5 refers to UK, Germany, Spain, Italy and France.

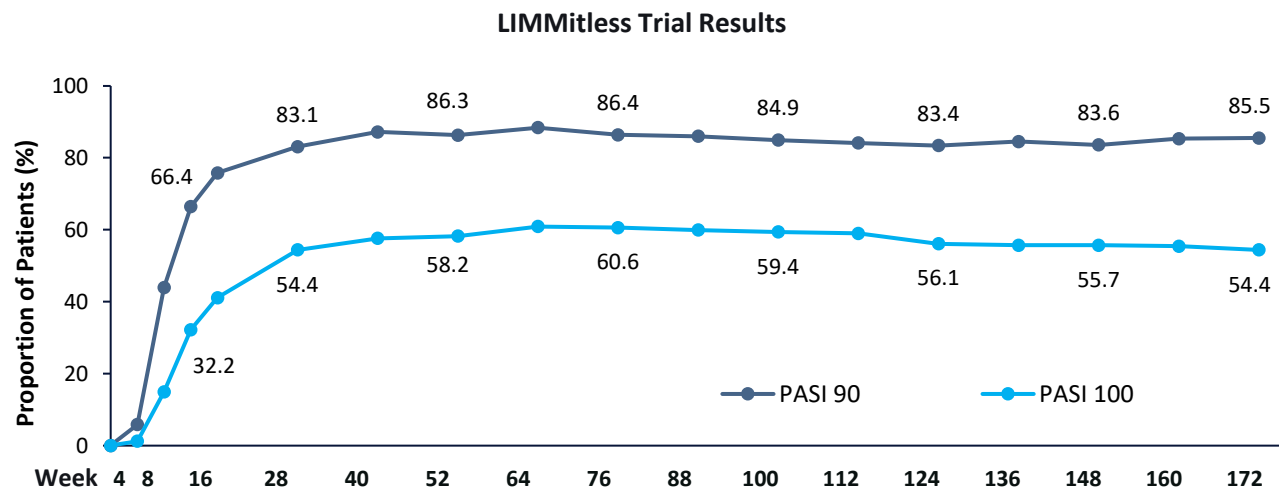
# Skyrizi Psoriasis

Delivering Durable Clearance with Sustained Efficacy Over 3.5 Years

**Superiority Data  
Against Agents in  
Three Biologic  
Treatment Classes**



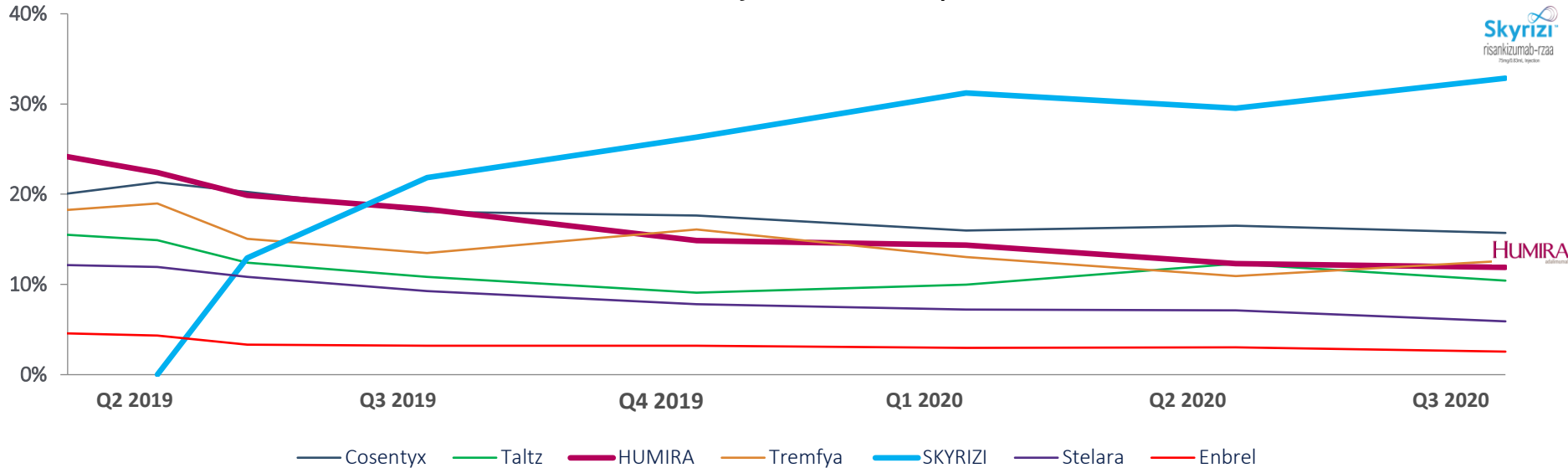
**Durability of  
Skin Clearance**



# Skyrizi Launch in PsO Continues to Demonstrate Strong Momentum

## Fastest Launch Uptake in PsO, Achieving U.S. In-Play Leadership Within First 3 Months

Total U.S. In-Play Patient Share | PsO



**➔ 33% U.S. In-Play Patient Share**

**➔ 13% U.S. Total Market Share**

**➔ 95% Commercial Access**

**\$5.5B\***

Expected 2025  
WW PsO Sales

Source: IQVIA, Accredo, Decision Resources Group and internal AbbVie estimates \*Includes a modest contribution from Derm PsA  
Note: In-Play patient share represents both new and switching patients

# Atopic Dermatitis Market

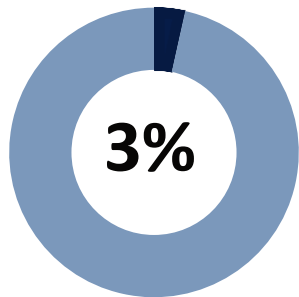
## 2020 Market Summary

**\$3.5B**

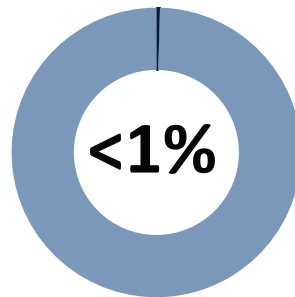
Estimated Global  
Market Value

**+58%**

U.S. TRx  
Growth



U.S.  
TIM-Penetration



EU5  
TIM-Penetration

## Key Market Trends



High unmet need and low penetration with only one TIM currently on market



Several emerging therapeutic options have the potential to significantly expand diagnosis and treatment within the eligible patient population



Patients are eager for more efficacious therapy given highly disruptive nature of disease burden

Sources: IQVIA, Accredo, Decision Resources Group, Symphony Health Patient Data, AbbVie estimates.

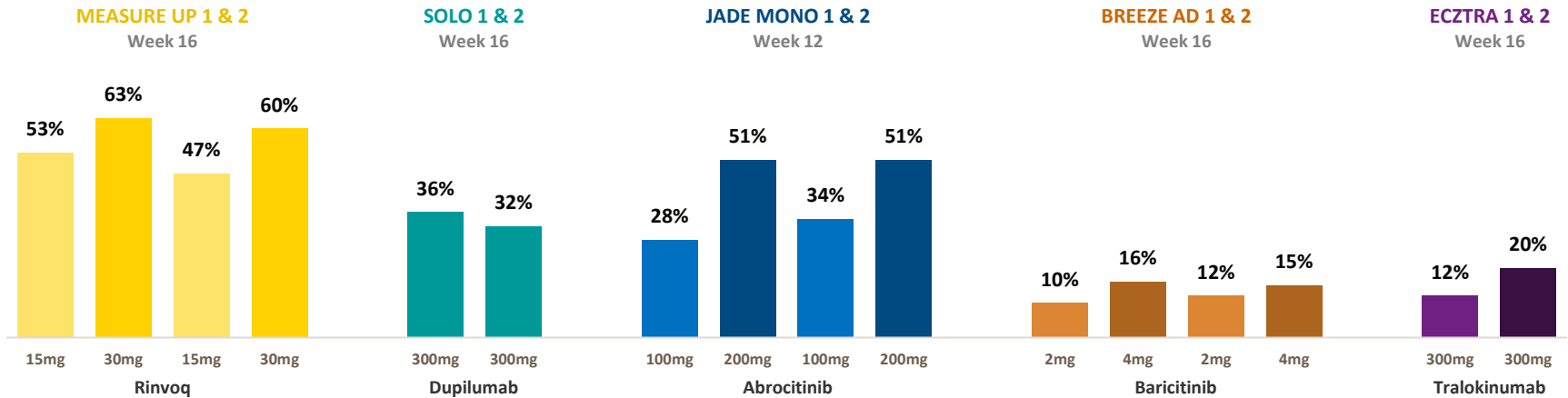
Note: TIM-penetration refers to TIM-treated patients as a percent of the total drug-treated patient population. AbbVie estimates approximately 110,000 TIM-treated AD patients in the U.S. and approximately 23,000 TIM-treated AD patients in EU5. EU5 refers to UK, Germany, Spain, Italy and France.

# Rinvoq in Moderate-to-Severe Atopic Dermatitis

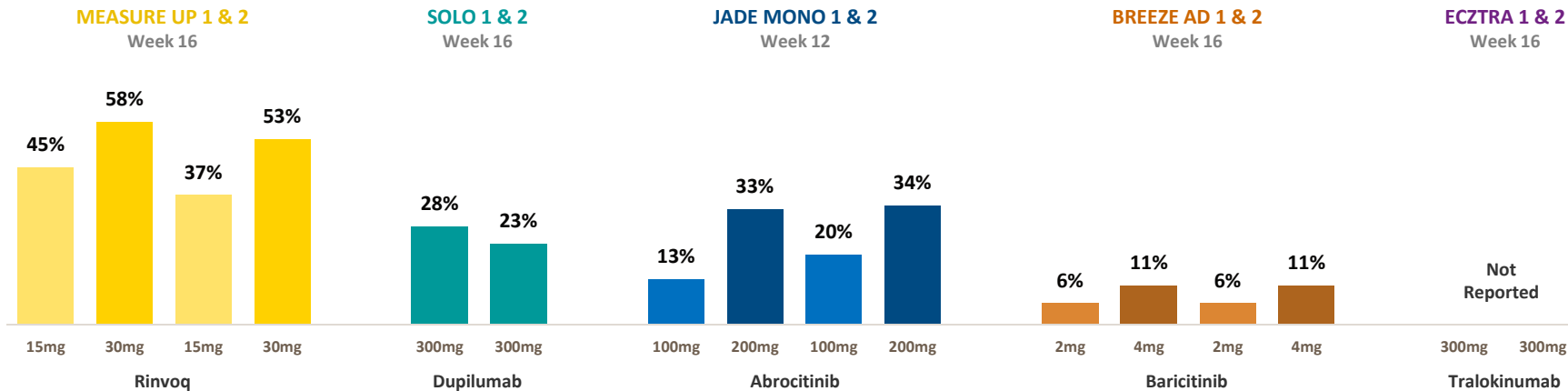
## Phase 3 Studies Show Robust Levels of Skin Clearance as Monotherapy in Patients with Moderate-to-Severe Atopic Dermatitis

Data not from head-to-head studies

### Placebo-Adjusted EASI 75 Response Rates @ Week 12/16



### Placebo-Adjusted EASI 90 Response Rates @ Week 12/16

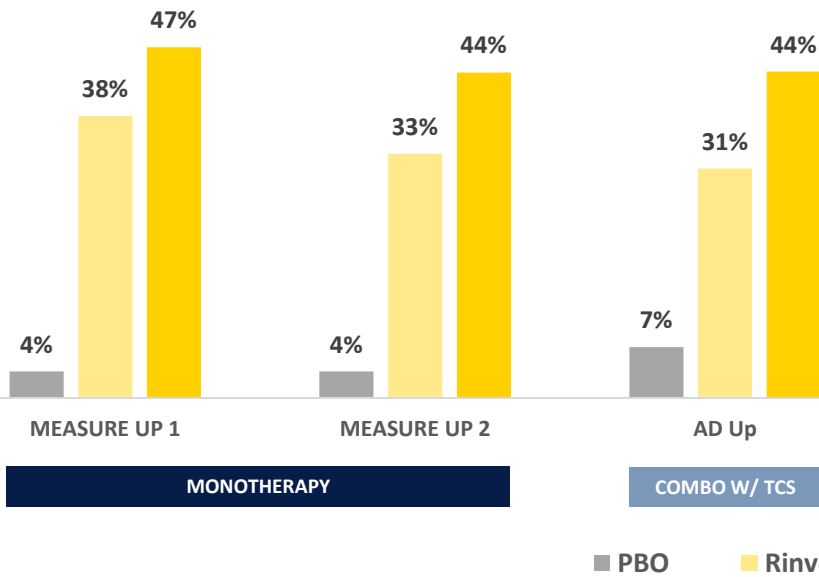


The data presented above are not from a head-to-head study; the data were derived from AbbVie's Measure Up 1 & 2 studies, Regeneron's SOLO 1 & 2 studies, Pfizer's JADE MONO 1 & 2 studies, Eli Lilly's BREEZE AD 1 & 2 studies and LEO Pharma's ECZTRA 1 & 2 studies. There are additional Phase 3 data for Rinvoq, dupilumab, abrocitinib, baricitinib and tralokinumab not shown above. Rinvoq, abrocitinib, baricitinib and tralokinumab have not been approved in AD and their safety and efficacy in this indication has not been evaluated by regulatory agencies.

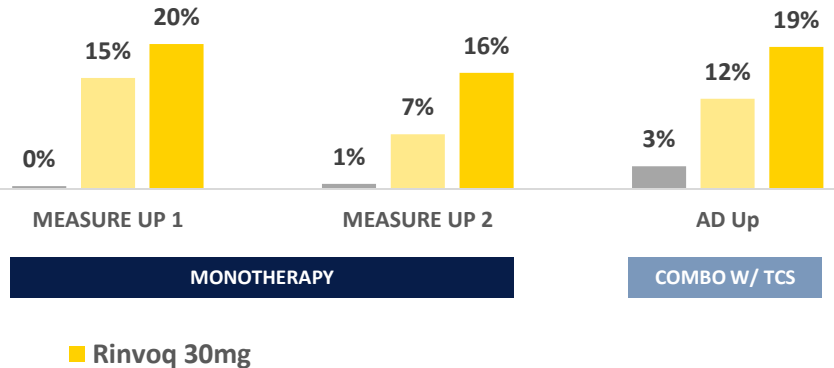
# Results of Rinvoq Registrational Program in Atopic Dermatitis

## Rinvoq Rapidly Improved Skin Disease Activity and Itch Across Phase 3 Program in Moderate-to-Severe Atopic Dermatitis

Proportion of Patients Achieving EASI 75 at Week 2



Proportion of Patients with Improvement in Worst Pruritus Score  $\geq 4$  at Week 1



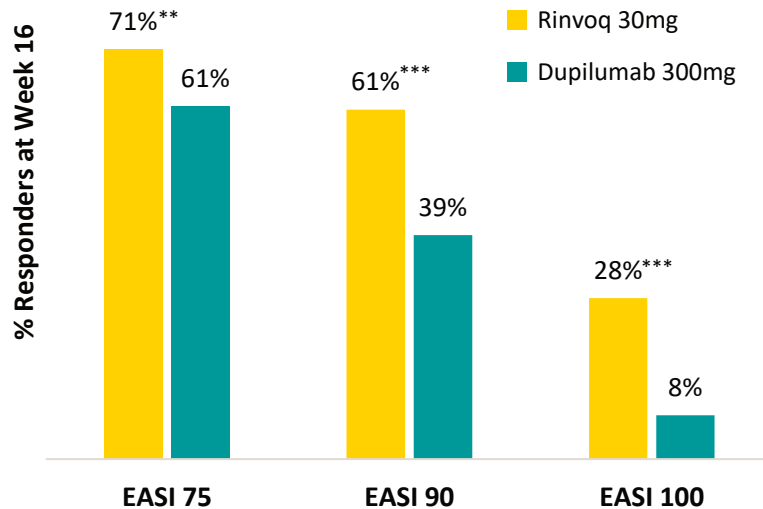
■ PBO ■ Rinvoq 15mg ■ Rinvoq 30mg

Rinvoq has not been approved in AD and its safety and efficacy in this indication has not been evaluated by regulatory agencies. Based on results from Rinvoq's Phase Measure Up 1, Measure Up 2 and AD Up studies. TCS = topical corticosteroids

# Results of Rinvoq Heads-Up Trial

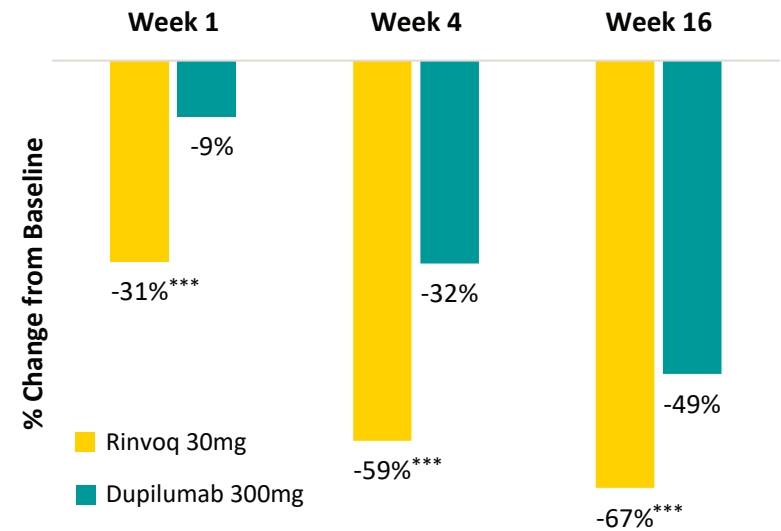
## Rinvoq Achieved Superiority to Dupilumab On Primary & All Ranked Secondary Endpoints

### Rinvoq Achieved Superiority to Dupilumab on Stringent EASI Thresholds at Week 16



### Rinvoq Provided Faster and Significantly Greater Improvements in Itch

(% Change from Baseline in Worst Pruritus Numerical Rating)



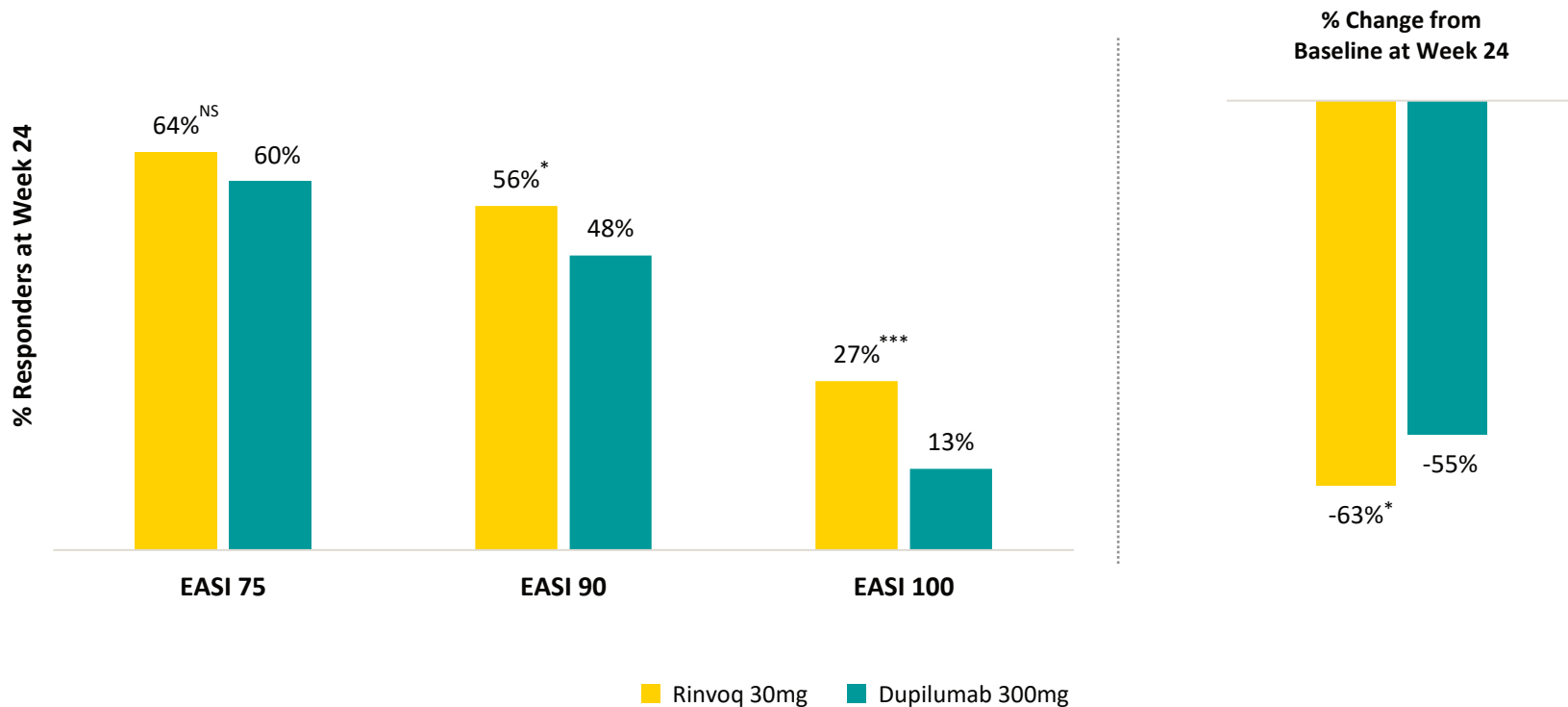
- Rinvoq's safety profile in the Phase 3 Heads Up trial was consistent with previous studies in AD.
- No reports of malignancies or MACE; one death due to bronchopneumonia associated with influenza A in patients treated with Rinvoq.
- Serious infections were reported infrequently in the Rinvoq and dupilumab treatment groups (1.1 percent in patients who received Rinvoq and 0.6 percent in patients who received dupilumab).
- SAE's occurred in 2.9 percent and 1.2 percent of patients receiving Rinvoq and dupilumab, respectively.

\*p-value < 0.05; \*\*0.001 < p-value ≤ 0.01; \*\*\*p-value ≤ 0.001. Rinvoq has not been approved in AD and its safety and efficacy in this indication has not been evaluated by regulatory agencies.

# Results of Rinvoq Heads-Up Trial

## Rinvoq 30mg Efficacy Advantage Over Dupilumab Maintained Through Week 24

### Rinvoq Skin and Itch Efficacy Advantage Over Dupilumab Maintained Through Week 24



Nominal p-values: \* <0.05, \*\* <0.01, \*\*\* <0.001, NS = not significant. Percent Improvement in Pruritus refers to Percent Change from Baseline in Worst Pruritus Numerical Rating at week 24. Rinvoq has not been approved in AD and its safety and efficacy in this indication has not been evaluated by regulatory agencies. Based on results from Phase 3 Heads Up study.



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GASTROENTEROLOGY

# Gastroenterology at a Glance

Opportunity to Drive Higher Remission Rates and Endoscopic Improvements with Rinvoq, Skyrizi and AbbVie's Earlier Stage Pipeline Programs

## Market

**\$22B**

Estimated 2020 Global Gastroenterology Market Value

**+14%**

U.S. Gastroenterology Market TRx Growth in 2020

**40%**

U.S. TIM-Penetration in Gastroenterology

**26%**

EU5 TIM-Penetration in Gastroenterology

## AbbVie

**34%**

Humira U.S. Crohn's Disease **Total** Market Share

**29%**

Humira U.S. Ulcerative Colitis **Total** Market Share

**27%**

Gastroenterology Portion of AbbVie Immunology Sales

**6**

Gastroenterology Programs in Development

Note: Gastroenterology includes CD and UC.

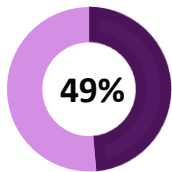
Sources: IQVIA, Accredo, Decision Resources Group, Symphony Health Patient Data, AbbVie estimates.

# Inflammatory Bowel Disease Markets

## CD 2020 Market Summary

**\$14B**

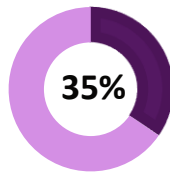
Estimated Global  
Market Value



U.S.  
TIM-Penetration

**+13%**

U.S. TRx  
Growth

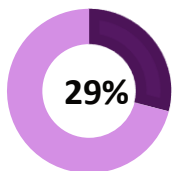


EU5  
TIM-Penetration

## UC 2020 Market Summary

**\$7.5B**

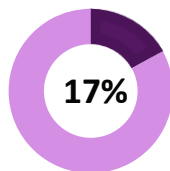
Estimated Global  
Market Value



U.S.  
TIM-Penetration

**+16%**

U.S. TRx  
Growth



EU5  
TIM-Penetration

## Key Market Trends



Innovations in IBD expected to drive increases in TIM-treated patients over the next 5 years



Novel therapies will address unmet needs including low remission rates, durability of response, and long-term safety



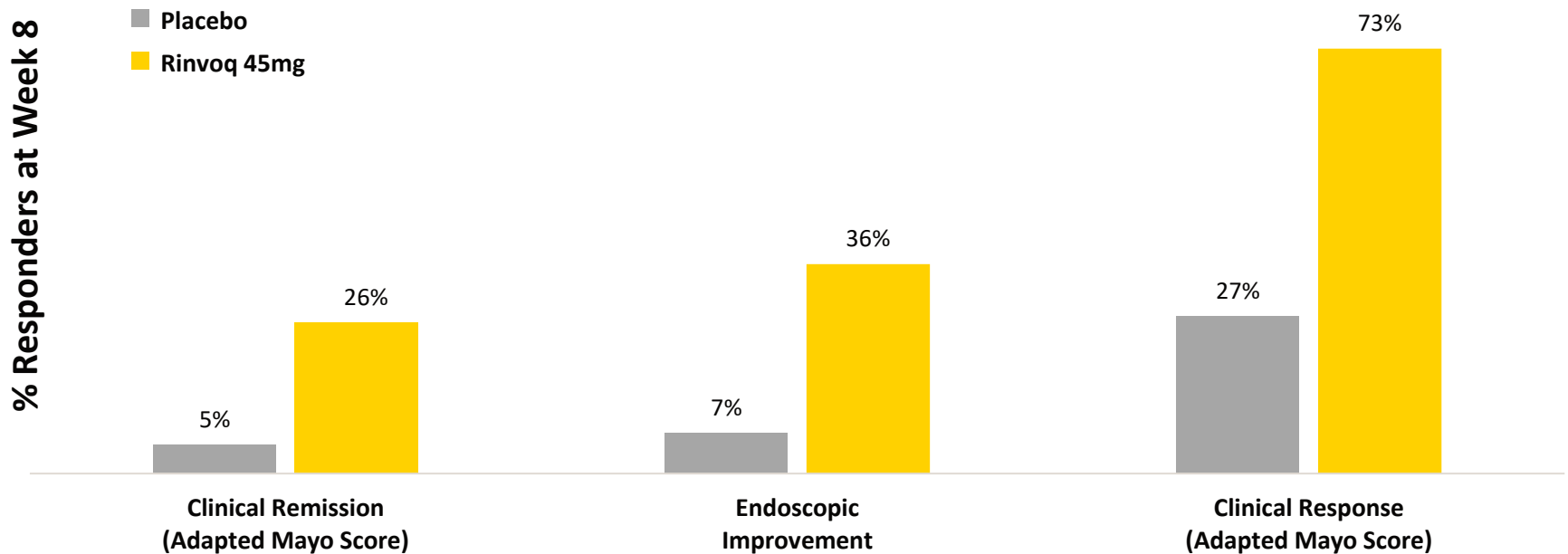
Accelerated growth in TIM-IR segment as more advanced options for patients emerge

Sources: IQVIA, Accredo, Decision Resources Group, Symphony Health Patient Data, AbbVie estimates.

Note: TIM-penetration refers to TIM-treated patients as a percent of the total drug-treated patient population. AbbVie estimates approximately 396,000 and 203,000 TIM-treated CD and UC patients in the U.S., respectively, and approximately 177,000 and 91,000 TIM-treated CD and UC patients in EU5, respectively. EU5 refers to UK, Germany, Spain, Italy and France.

# Rinvoq Top-line Results from Phase 3 U-ACHIEVE in Ulcerative Colitis

Rinvoq 45mg was well tolerated and no new safety risks were observed in the Phase 3 U-Achieve Trial. No reports of active TB, malignancy, adjudicated GI perforation, adjudicated MACE and VTE, or death.



## Rinvoq demonstrated strong results in both Non-Bio-IR and Bio-IR populations

- 26% PBO-adjusted Clinical Remission in Non-Bio-IR patients (47% of total)
- 18% PBO-adjusted Clinical Remission in Bio-IR patients (53% of total)

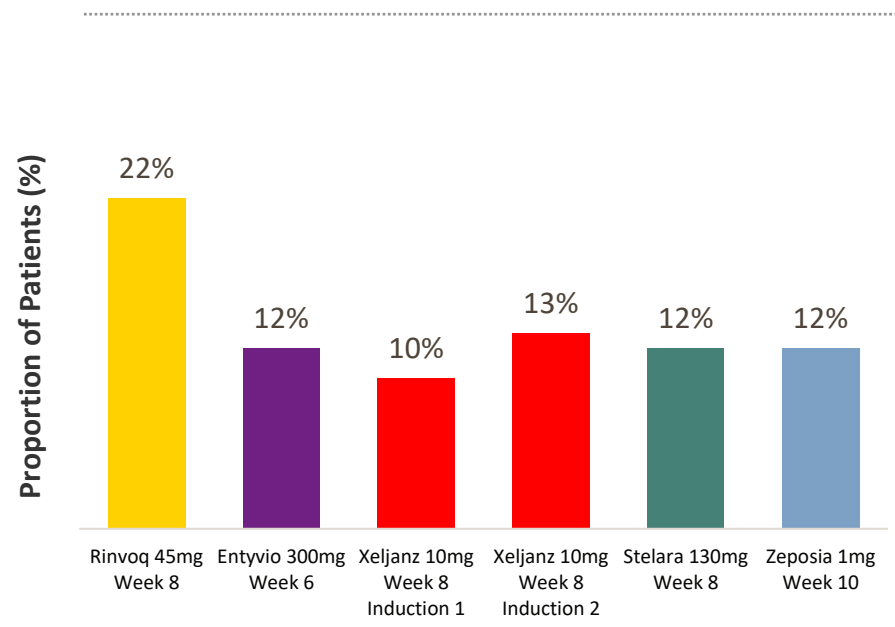
Rinvoq has not been approved in UC and its safety and efficacy in this indication has not been evaluated by regulatory agencies. Data from Phase 3 U-ACHIEVE study. Bio-IR refer to patients with an inadequate response, loss of response, or intolerance to biologic therapies; Non-Bio-IR refers to patients who have had inadequate response or loss of response to conventional therapy but have not failed biologic therapy (approximately 95% of Non-Bio-IR participants were Bio-Naïve).

Data not from head-to-head studies

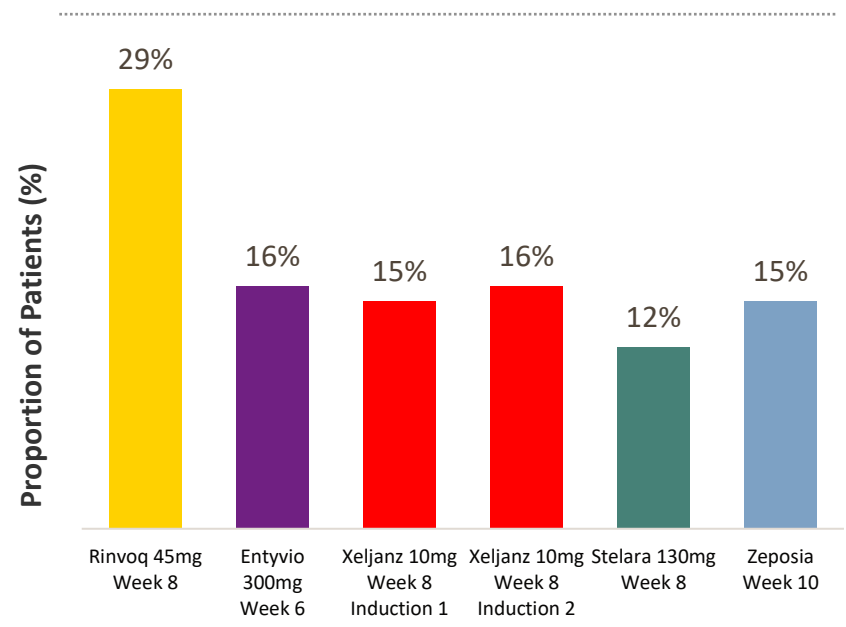
# Rinvoq Results in Phase 3 Ulcerative Colitis Study

## Compelling Levels of Clinical Remission and Endoscopic Improvement

### Placebo-Adjusted Clinical Remission



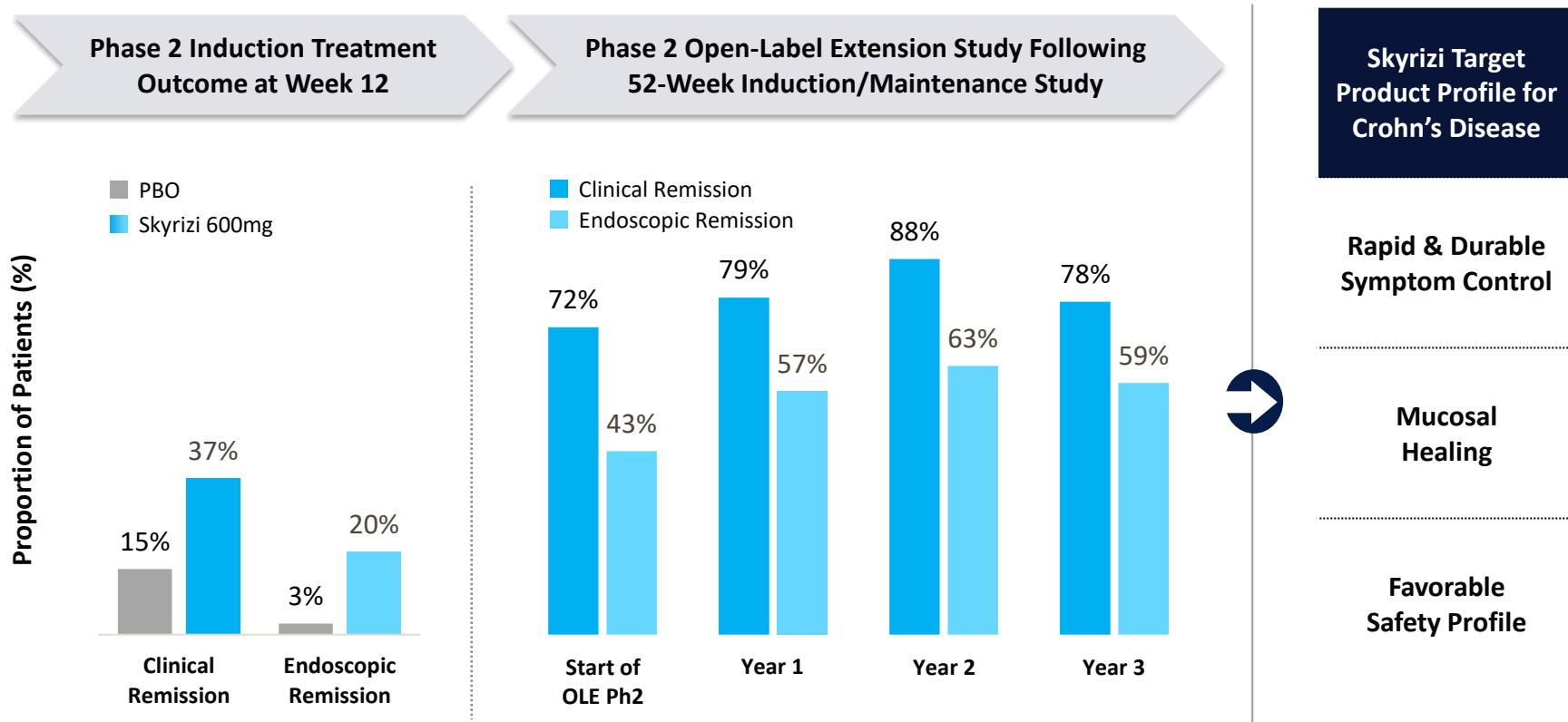
### Placebo-Adjusted Endoscopic Improvement



The data presented above are not from a head-to-head study; the data were derived from AbbVie’s Phase 3 U-ACHIEVE induction study, Takeda’s GEMINI study, Pfizer’s OCTAVE 1 and 2 studies, Janssen’s UNIFI study, and Bristol Myers Squibb’s TRUE NORTH study. There are additional Phase 3 data for Entyvio, Xeljanz and Stelara not shown above. Endoscopic Improvement: endoscopic score  $\leq 1$ . Definition of Clinical Remission (CR) varies across studies. Rinvoq CR based on Adapted Mayo ( $\leq 2$ , with SFS  $\leq 1$  and not greater than baseline, RBS=0, and endoscopic subscore  $\leq 1$ ); Xeljanz CR based on Full Mayo Score ( $\leq 2$  and all subscore  $\leq 1$ , RBS=0); Entyvio CR based on Full Mayo Score ( $\leq 2$  and all subscore  $\leq 1$ ); Stelara CR based on Adapted Mayo (Both endoscopic subscore and SFS  $\leq 1$  and RBS=0); Zeposia CR based on Adapted Mayo Score ( SFS  $\leq 1$  and decrease from Baseline by  $>1$  point, RBS=0, endoscopy score  $\leq 1$  without friability). Rinvoq has not been approved in UC and its safety and efficacy in this indication has not been evaluated by regulatory agencies.

# Phase 2 Results for Skyrizi in Crohn's Disease

Potential for a Competitive Profile Based on Phase 2 Induction & Maintenance Data



## Phase 3 Induction and Maintenance Data Expected in 2021

Induction data from Ph2 M15-993 study, Open Label Extension (OLE) data from Ph2 M15-989. Clinical remission (CDAI<150); endoscopic remission (CDEIS score of 4 or less (for patients with initial isolated ileitis a score of 2 or less)). Week 12 data analyzed as non-responder imputation and OLE data analyzed as observed. Patients who successfully completed the preceding Ph2 study enrolled into the OLE study and received open-label 180 mg subcutaneous maintenance dose of Skyrizi every 8 weeks. Year 1 of OLE study refers to week 48 for both clinical remission and endoscopic remission; Year 2 refers to week 112 for clinical remission and week 104 for endoscopic remission; Year 3 refers to week 160 for clinical remission and week 152 for endoscopic remission. Skyrizi has not been approved in CD and its safety and efficacy in this indication has not been evaluated by regulatory agencies.

# Exceptional International Launches

Expect Significant International Revenue Contribution



**~70** Countries Approved

**~60** Countries Approved

**~45** Countries with Access

**~25** Countries with Access

**>14K** Patients on Therapy

**>13K** Patients on Therapy

**~\$200M** Expected 2020 International Sales

**~\$75M** Expected 2020 International Sales

**~\$1.5B** Expected Risk-Adjusted International Sales in 2025

**~\$2.5B** Expected Risk-Adjusted International Sales in 2025

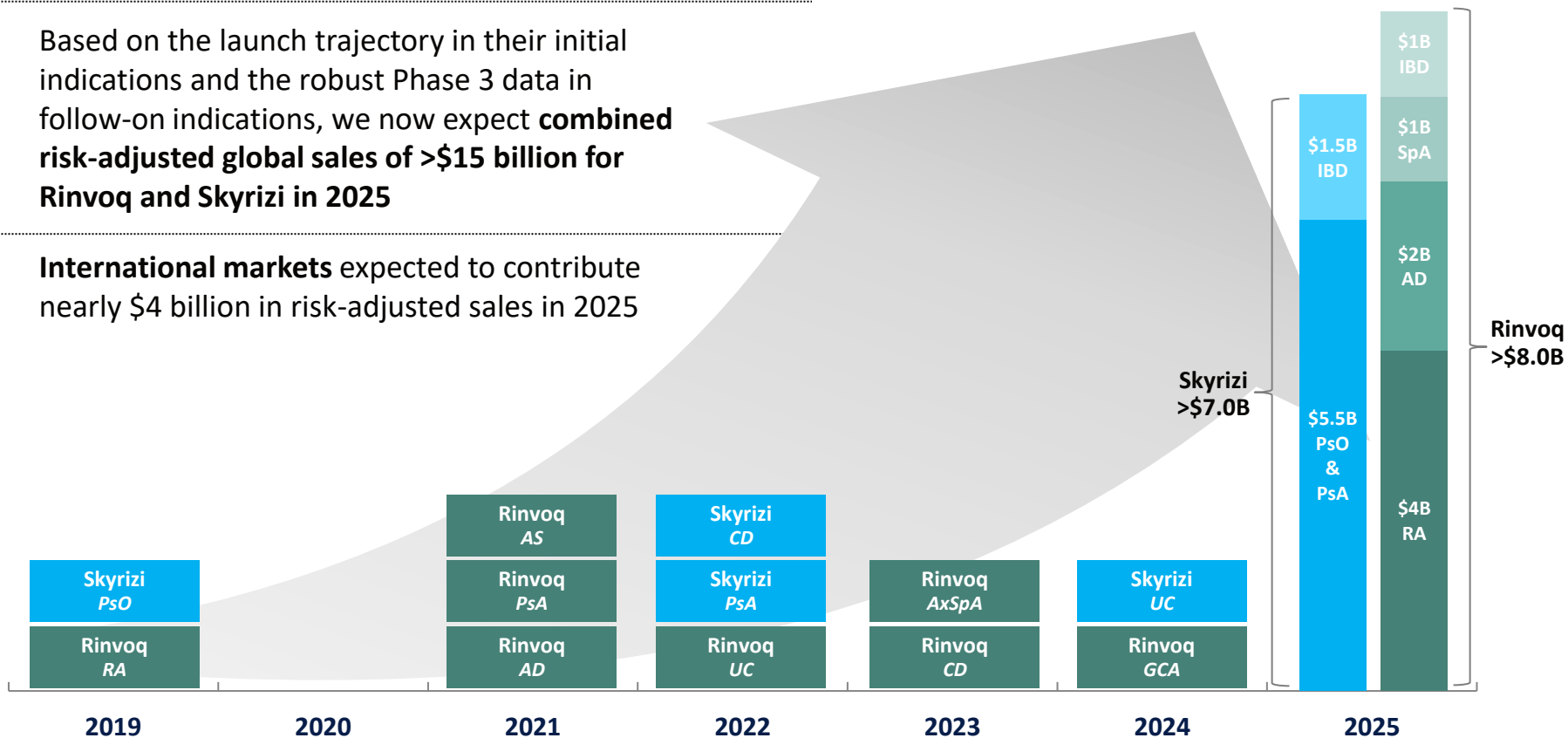
# Rinvoq and Skyrizi Represent Tremendous Long-Term Value

- Adding new indications in 2020-2025 timeframe and ramping to peak share 2025-2030, both **Rinvoq and Skyrizi expected to peak in early 2030s**

- Based on the launch trajectory in their initial indications and the robust Phase 3 data in follow-on indications, we now expect **combined risk-adjusted global sales of >\$15 billion for Rinvoq and Skyrizi in 2025**

- International markets** expected to contribute nearly \$4 billion in risk-adjusted sales in 2025

**>\$15.0B**  
Expected Combined  
Risk-Adjusted Global Sales



Rinvoq has not been approved in AS, PsA, AD, UC, Axial SpA, CD or GCA and Skyrizi has not been approved in PsA, CD or UC, and their safety and efficacy in these indications have not been evaluated by regulatory agencies.



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# ABBVIE IMMUNOLOGY R&D STRATEGY

# Immunology R&D Strategy

Focused on Redefining the Standard of Care in Core Areas and Expanding to New Disease Areas in Rheum/Derm/Gastro with High Unmet Need

## Core Disease Areas

### RHEUMATOLOGY

Achieve higher remission and halt disease progression

### DERMATOLOGY

Achieve durable skin clearance with an oral agent in PsO

### GASTROENTEROLOGY

Achieve higher and more durable remission rates and induce mucosal healing

## New Disease Areas

### LATE-STAGE PIPELINE

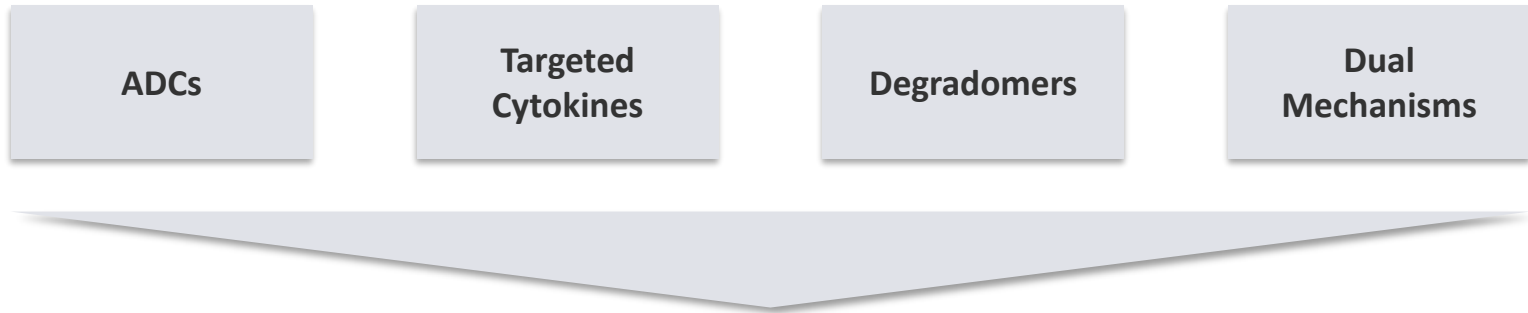
Expand Rinvoq to new indications such as atopic dermatitis and giant cell arteritis

### EARLY-STAGE PROGRAMS

Advance early pipeline to deliver in new diseases with minimal treatment options

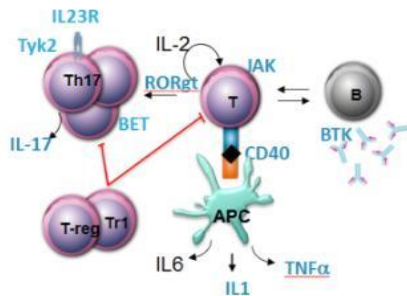
# Areas of Focus for Early-Stage Immunology Pipeline

Investment in Precise Immunologic Strategies, Well-Informed Dual Mechanisms, and Targeted Delivery Will Improve Clinical Performance and Sustain Leadership in Immunology



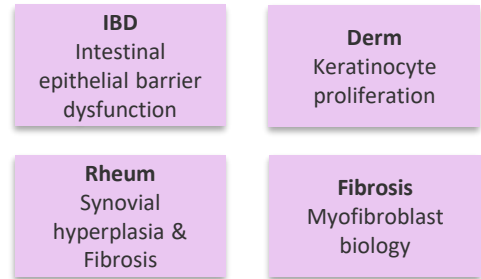
## Immunomodulation of Adaptive and Innate Cells

Advancement of JAK, BTK, RORγt, Tyk-2, and CD40



## Barrier Function & Tissue Repair

Target non-immune pathways and tissue dysfunction to enable dual mechanistic approaches

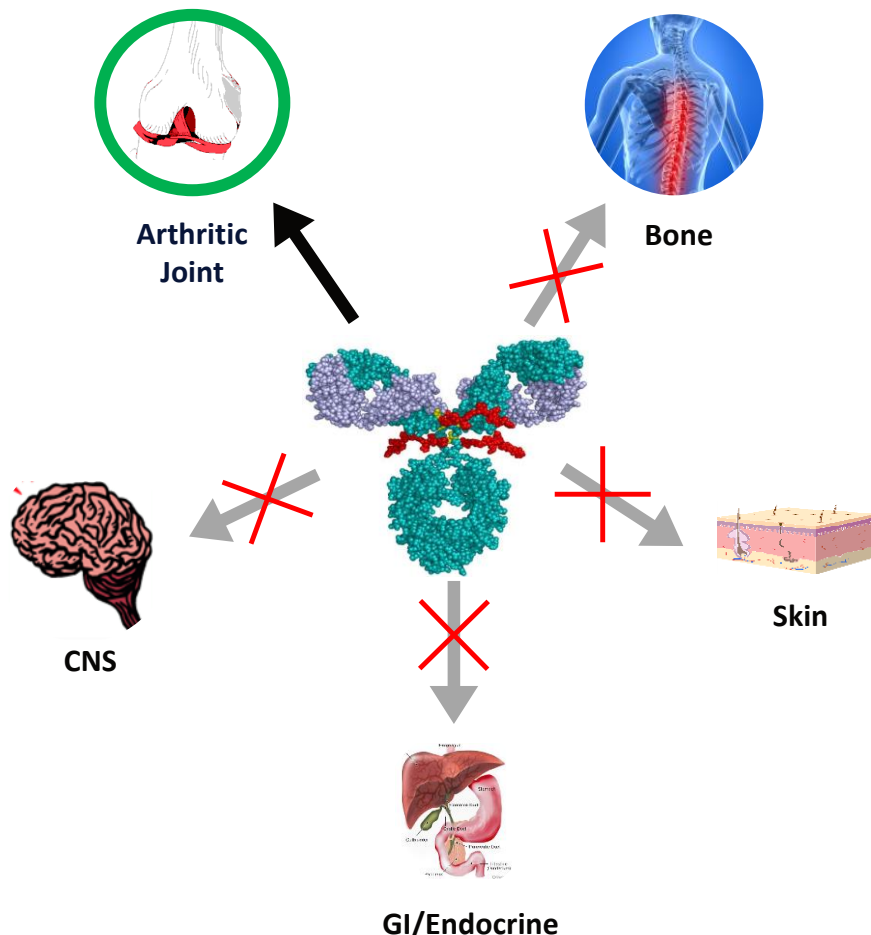


# AbbVie's Anti-TNF Steroid Antibody Drug Conjugate

## Novel Approach to Target Immunomodulation Without Steroid Side Effects

### TNF ADC Only Targets Inflamed Tissue

### Designed to Provide Transformational Efficacy in AbbVie's Core Indications



- Anti-TNF antibody and steroid therapies are very effective medicines often used in combination
- The use of steroids is limited due to severe side effects, even at low doses (< 5mg/day)
- Anti-TNF mAb is internalized on activated immune cells through its binding to transmembrane TNF
- The anti-TNF ADC will direct the steroid payload directly to inflammatory cells

AbbVie's anti-TNF steroid ADCs (ABBV-3373 and ABBV-154) have not been approved and their safety and efficacy have not been evaluated by regulatory agencies.

# Anti-TNF / Steroid Conjugate

## Designed to Provide Transformational Efficacy in AbbVie's Core Indications

### Rheumatoid Arthritis



Achieve durable remission and halt disease progression

### Crohn's disease



Improve clinical remission rates and induce mucosal healing

### Proof-of-Concept Established in RA

ABBV-3373 demonstrated significant improvement in disease activity in Phase 2 clinical trial in RA

Significantly greater reduction in DAS28 compared to the historical Humira and provided greater improvement on DAS28 than Humira based on in-trial data combined with historical data

ABBV-3373 did not show systemic glucocorticoid effects

Safety profiles of ABBV-3373 and Humira were similar

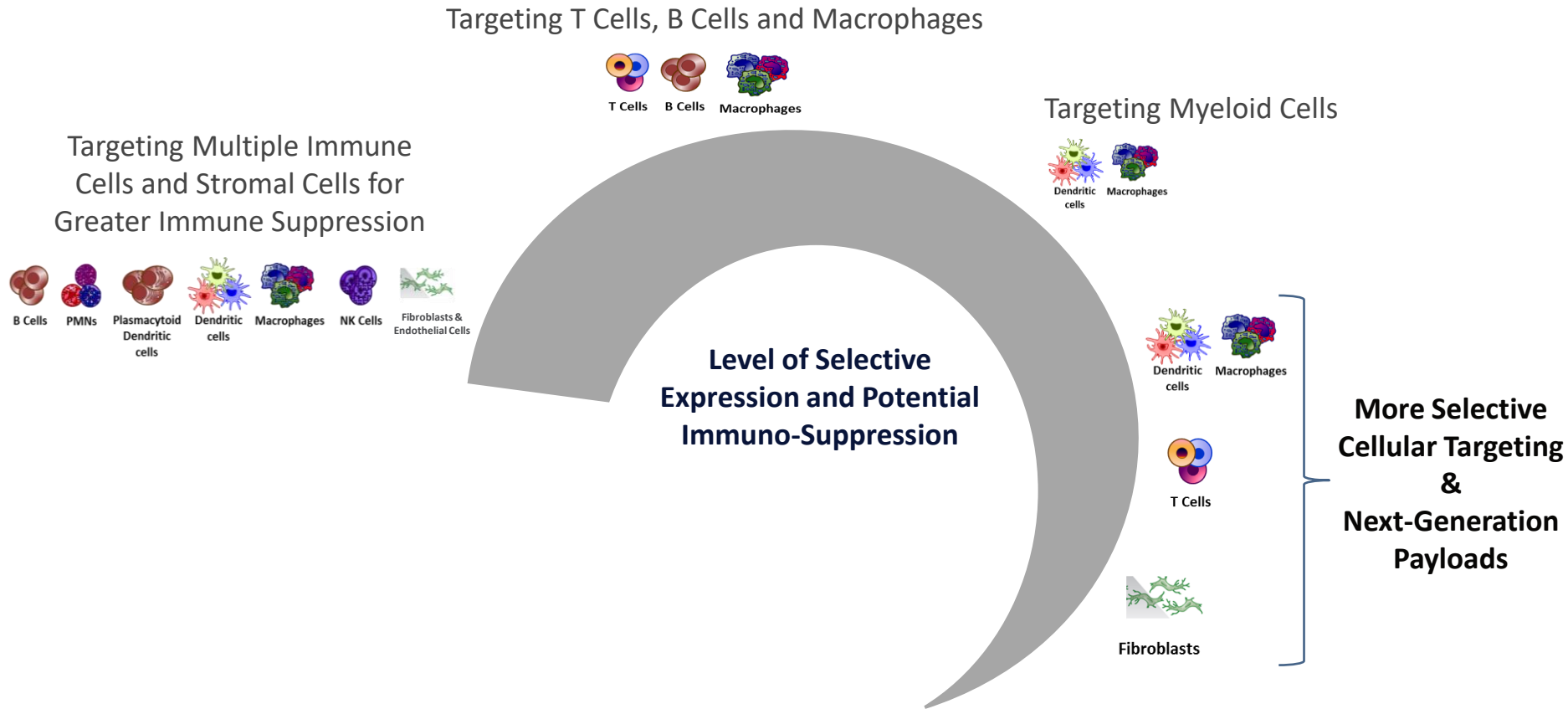
Advancing ABBV-154 (follow-on ADC to ABBV-3373) to Phase 2 dose-ranging study in RA in 1H 2021

AbbVie's anti-TNF steroid ADCs (ABBV-3373 and ABBV-154) have not been approved and their safety and efficacy have not been evaluated by regulatory agencies

# Targeting Strategy with Immunology ADC Platform

## Novel Approach to More Selectively Target Pathogenic Immune Cells

**Anchored by the Success of the Anti-TNF Steroid ADC in RA, the Next Generation Immunology ADC Platform Strategy Involves More Selectively Targeting Pathogenic Immune Cells with Novel Payloads**



**4 next-generation iADC programs in preclinical development targeting core and new indications (e.g. SLE, pSS, SSc, PMR, AD)**

# Opportunity to Pioneer Treatments in New Diseases Outside of AbbVie's Core Indications



Disease	Target Patient Population	Estimated Patient Population Size*	Approved TIMs Today
Systemic Sclerosis	Early and established diffuse cutaneous systemic sclerosis (dcSSc) patients	~91,000	1
Giant Cell Arteritis & Polymyalgia Rheumatica	Patients with active disease who have inadequate response to steroids	~210,000	1**
Systemic Lupus Erythematosus	Moderate to severe systemic lupus erythematosus and lupus nephritis patients	~70,000	1
Sjogren's Syndrome	Moderate to severe patients with glandular and extra-glandular disease	~78,000	0
Vitiligo, Prurigo Nodularis, Eosinophilic Esophagitis	Various	~670,000	0

**More than 15 programs in Discovery/Preclinical/Clinical development targeting these new disease areas**

\*Includes both US and EU5 estimated patient population size.

\*\* Approved TIM refers to GCA indication

# AbbVie R&D Pipeline – Select Assets and Programs

## Phase 1

- **ABBV-157 (ROR $\gamma$ T) PsO**
- **ABBV-022 (IL-22) UC**
- ABBV-151 (GARP+TGF $\beta$ 1) Solid Tumors
- ABBV-155 (BCL-xL ADC) Solid Tumors
- ABBV-181 (PD-1) Solid Tumors
- ABBV-184 (Survivin-CD3) AML, NSCLC
- ABBV-368 (OX40) Solid Tumors
- ABBV-467 (MCL) Heme Tumors
- ABBV-621 (TRAIL) Solid/Heme Tumors
- ABBV-744 (BET) AML
- ABBV-927 (CD40) Solid Tumors
- ABBV-CX-2029 (CD71) Solid/Heme Tumors
- ABBV-647 (PTK7 ADC) NSCLC
- ABBV-011 (SEZ6 ADC) SCLC
- VENCLEXTA (Bcl-2) ALL
- VENCLEXTA (Bcl-2) Solid Tumors
- CCW702 (CD3-PSMA) Prostate Cancer
- CLBR001/SWI019 (sCAR-T) Heme Tumors
- GEN1044 (CD3x5T4) Solid Tumors
- GEN3009 (CD37) Heme Tumors
- JAB-3068 / JAB-3312 (SHP2) Solid Tumors
- HPN-217 (CD3-BCMA) MM
- TNB-383B (CD3-BCMA) MM
- TTX-030 (CD39) Solid Tumors
- ABBV-0805 ( $\alpha$ -Synuclein) PD
- AL002 (TREM2) AD
- AL003 (CD33) AD
- Vraylar (D2,5-HT1A, 5-HT2A) ASD
- ABBV-4083 (TylAMac) Filariar Diseases
- CF Triple Combo (CFTR-C1/CFTR-C2/CFTR-P)
- AGN-242266 (FXR) NASH
- AGN-231868 (Chemokine) Dry Eye
- AGN-242428 (RoR $\gamma$ ) Dry Eye
- AGN-241622 (Alpha2) Presbyopia

## Phase 2

- **ABBV-154 (TNF-Steroid ADC) RA**
- **Rinvoq (JAK 1) HS**
- **Skyrizi (IL-23) HS**
- **ABBV-599 (BTK/JAK) SLE**
- **Ravagalimab (CD40) UC**
- **ALPN-101 (ICOS/CD28) SLE**
- Imbruvica (BTK) Solid Tumors
- Teliso-V (cMet ADC) NSCLC
- GEN3013 (CD3xCD20): Heme Tumors
- ABBV-8E12 (Tau) AD
- Elezanumab (RGMa) MS
- Elezanumab (RGMa) Stroke
- Elezanumab (RGMa) SCI
- Elagolix (GnRH) PCOS
- Armour Thyroid (T3T4) Hypothyroidism
- CVC/Tropifexor (CCR2/CCR5, FXR) NASH
- Abicipar (VEGF-A) DME
- BoNTE (SNARE) Glabellar Lines
- Botox (SNARE) Platysma Prominence

## Registrational / Phase 3

- **Rinvoq (JAK 1) CD**
- **Rinvoq (JAK 1) UC**
- **Rinvoq (JAK 1) GCA**
- **Rinvoq (JAK 1) Axial SpA**
- **Skyrizi (IL-23) CD**
- **Skyrizi (IL-23) UC**
- **Skyrizi (IL-23) PsA**
- Imbruvica (BTK) 1L FL
- Imbruvica (BTK) 1L MCL
- Imbruvica (BTK) R/R MCL
- Imbruvica (BTK) R/R FL/MZL
- Imbruvica (BTK) 1L CLL
- Imbruvica (BTK) 1L cGvHD
- Veliparib (PARP) BRCA Breast Cancer
- Veliparib (PARP) 1L Ovarian Cancer
- Veliparib (PARP) NSCLC
- Venclexta (BCL-2) 1L CLL
- Venclexta (BCL-2) AML Maintenance
- Venclexta (BCL-2) R/R MM t(11;14)
- Venclexta (BCL-2): MDS
- Navitoclax (BCL-2/BCL-xL) Myelofibrosis
- ABBV-951 (dopamine receptor) PD
- Atogepant (CGRP) Migraine Prophylaxis
- Vraylar (D2,5-HT1A, 5-HT2A) aMDD
- Elagolix + Hormonal Add-Back (GnRH) EM
- Aztreonam/Avibactam (PBP3) Infection
- Cenicriviroc (CCR2/CCR5) NASH
- AGN-190584 (Muscarinic) Presbyopia
- Botox (SNARE) Masseter Prominence
- NivobotulinumtoxinA (SNARE) Facial Lines

## Submitted

- Rinvoq (JAK 1) PsA
- Rinvoq (JAK 1) Atopic Derm
- Rinvoq (JAK 1) AS

■ Immunology Assets



# Summary

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AbbVie has been the market leader in Immunology for more than a decade and is well-positioned for sustained leadership

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High unmet need, improving therapies and increasing penetration will continue to drive growth in the global Immunology market

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AbbVie's industry-leading sales force, medical affairs, market access and patient support capabilities will drive strong execution to maximize the value of our Immunology portfolio

---

Skyrizi and Rinvoq are highly differentiated assets and represent tremendous long-term value, with risk-adjusted sales in 2025 expected to exceed \$15 billion

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Immunology R&D strategy aimed to redefine the standard-of-care in core indications and expand into new disease areas with high unmet need

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