Q4 & YE 2021 Financial Results Presentation

March 1, 2022

Forward-Looking Statements

This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1955 ("PSLRA") relating to, among other things, the commercial success of TAVALISSE in the U.S. and TAVLESSE in Europe; including expectations related to the potential and market opportunity for fostamatinib as therapeutic for, among other things, wAIHA and COVID-19; the commercialization of fostamatinib in international markets; Rigel's and its partners' ability to further develop its clinical stage and early-stage product candidates and programs including its IRAK1/4 inhibitor program; and Rigel's partnering efforts.

Any statements contained in this presentation that are not statements of historical fact may be deemed to be forward-looking statements and as such are intended to be covered by the safe harbor for "forward-looking statements" provided by the PSLRA. Words such as "potential", "may", "expects", and similar expressions are intended to identify these forward-looking statements and inherently involve risks and uncertainties. These forward-looking statements are based on Rigel's current expectations and information available to Rigel on the date of this presentation. Actual results and the timing of events could differ materially from those anticipated in such forward looking statements due to a number of factors that involve substantial known and unknown risks and uncertainties, which include, without limitation, risks and uncertainties associated with the commercialization and marketing of TAVALISSE; risks that the FDA, EMA or other regulatory authorities may make adverse decisions regarding fostamatinib; risks that TAVALISSE clinical trials may not be predictive of real-world results or of results in subsequent clinical trials; risks that TAVALISSE may have unintended side effects, adverse reactions or incidents of misuses; the availability of resources to develop Rigel's product candidates; market competition; as well as other risks detailed from time to time in Rigel's reports filed with the Securities and Exchange Commission, including its Annual Report on Form 10-K for the year ended December 31, 2021 and subsequent filings. Rigel does not undertake any obligation to update forward-looking statements and expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein, except as required by law.

Please see www.TAVALISSE.com for Important Safety Information and full prescribing information.

Introduction & Highlights

Raul Rodriguez

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Rigel Participants

Raul Rodriguez

President & Chief Executive Officer

Dolly Vance

Executive Vice President, Corporate Affairs & General Counsel

Dave Santos

Executive Vice President & Chief Commercial Officer

Wolfgang Dummer, M.D., Ph.D.

Executive Vice President & Chief Medical Officer

Dean Schorno

Executive Vice President & Chief Financial Officer

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Successfully Executing on Key Value Drivers

Grow Sales in ITP

Bottles shipped to patients and clinics continues to grow

New patient starts continue to grow

Expanded field force to accelerate our reach among prescribers

>$2B[2]

Capitalize on wAIHA[1] Opportunity

Pivotal Phase 3 FORWARD study enrollment complete

Topline data expected mid-2022

Potential first to market therapeutic for wAIHA

Potential $1B US[3]

Explore Fostamatinib in COVID-19[1] & Beyond

Comprehensive clinical program for the treatment of COVID-19

Rigel-led Phase 3 enrollment progressing with 265 pts as of February 28, 2022

Positive results from NHLBI/NIH Phase 2 clinical trial published in the peer-reviewed journal, *Clinical Infectious Disease*

>$2B[4]

Advance Pipeline Programs

Advancing development of our IRAK1/4 inhibitor program with Phase 1b study in low-risk MDS initiating

Progressing both RIPK1 inhibitor programs in collaboration with Lilly

Substantial

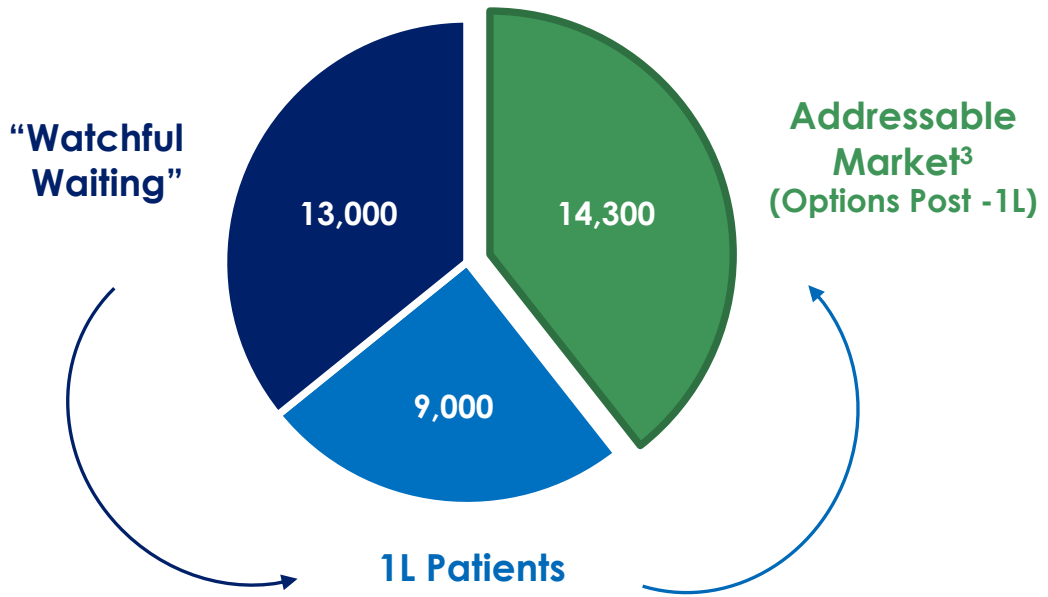
MARKET OPPORTUNITY

[1]Investigational compound in this indication and has not been submitted for FDA review. [2]Company's internal estimate based on 2018 sales of ITP therapies used for steroid-refractory patients. [3]DelveInsight Research "Warm Autoimmune Hemolytic Anemia [wAIHA] – Market Insight, Epidemiology, and Market Forecast". [4]Johns Hopkins University COVID-19 Tracker, COVID Tracking Project, IntegriChain 852 and 867 and HHS admissions.
Please see slides 36 & 37 for Important Safety Information. Please visit www.TAVALISSE.com for full prescribing information.

Capitalize on wAIHA Opportunity

Positioned to Capitalize on Warm AIHA Opportunity

36,000 US Adult wAIHA Patients[1,2]



Patients cycle on and off treatment (Similar to ITP)

No therapy approved by FDA - significant unmet medical need

- Currently used therapies (corticosteroid and rituximab) broadly suppress immune system

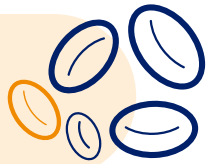
Phase 3 pivotal trial provides potential first mover advantage

Synergies with ITP to create a highly accretive opportunity

- Commercial infrastructure with established relationships in place
- Same targeted physicians and product profile

Sources: 1. Prevalence: A. Zanella, et al, , haematologica 2014; 99(10) 2. % Warm AIHA: T. Kalfa; Hematology Am Soc Hematol Educ Program. 2016 Dec 2; 2016(1): 690–697
3. Quantitative Physician Research, May 2021, n = 150;

Warm Autoimmune Hemolytic Anemia (wAIHA)



- **Autoimmune disorder characterized by low hemoglobin levels (<10 g/dL) and measures of hemolysis[1]**

- **Clinical manifestations** include fatigue, dyspnea, palpitations, severe weakness, enlarged spleen or liver, heart failure and fainting[2]

- **Increased risk of thromboembolic events[3]**
  - Incidence of TEEs is highest early after diagnosis and TEEs are more common in patients with severe hemolysis (Hgb <8 g/dL and high LDH levels)

- **Mortality rate of 8-11%[4-6]**

Sources: 1. Barcellini W, Fattizzo B. Clinical Applications of Hemolytic Markers in the Differential Diagnosis and Management of Hemolytic Anemia. Dis Markers. 2015;2015:635670. doi: 10.1155/2015/635670. Epub 2015 Dec 27. 2. Brodsky, R., N Engl J Med 2019; 381:647-654 3. Audia, S., PLoS One. 2018 Nov 8;13(11):e0207218. 4. J Autoimmun. 2007;29(1)1-9 5. Petz, LD Immune Haemolytic Anemias 2004. 6. Am J Hematol. 2014;89(9):150-155

Current Treatment Landscape for WAIHA is Limited

There are currently no approved therapies for wAIHA patients and available therapies are limited by waning effectiveness over time and side effects

First-Line

Steroids

- Suppress immune function, reduce antibody production resulting in decrease red blood cell destruction
- Standard first-line therapy for newly diagnosed patients
- Overtime treatment side effects may outweigh potential benefits
- Most patients relapse upon discontinuation

Second-Line

Rituximab

- B cell depletion
- Currently used as second-line therapy
- Immunosuppressive with risk of infection

Third-Line +

Splenectomy

- Permanent removal of organ
- Surgical risks of complications, prolonged recovery -- challenging for some patients (older, significant comorbidities or weakened)
- Increased risk of thromboembolic events
- Life-long risk of serious infection
- Only ~40% complete remission

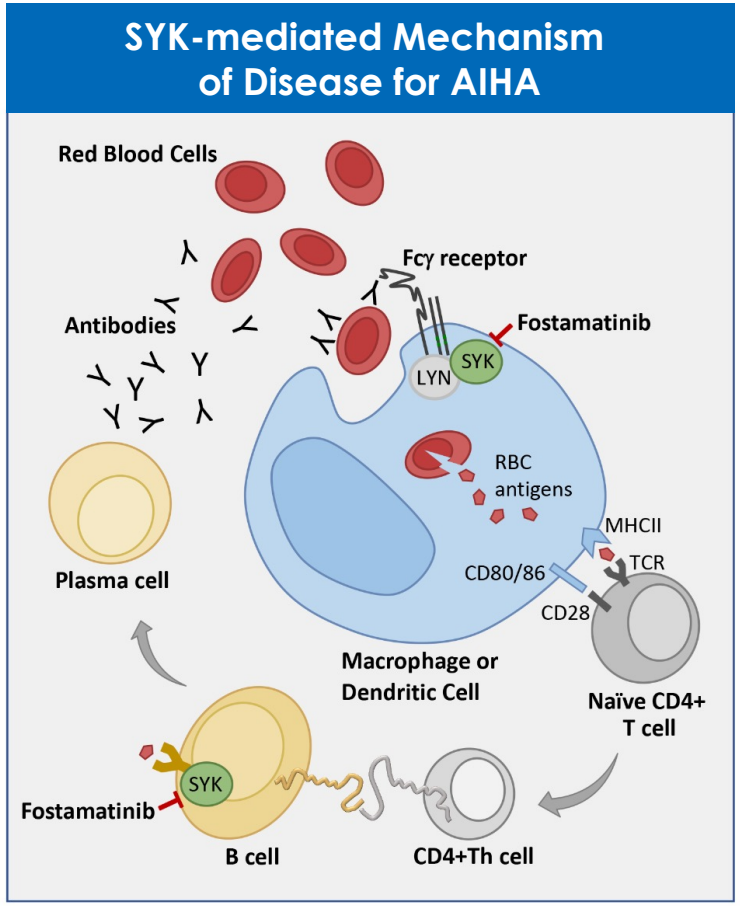
Immunosuppressive and Cytotoxic Medications

- Immunosuppressive with risk of infection
- Limited effectiveness

- **Patients cycle on and off treatment and in between treatments**
- **Lines of therapy are not clearly defined, and therapies used in combination**

Jäger, U., Blood Reviews 41 (2020) 100648

A Targeted Approach in wAIHA: Inhibition of SYK Activation[1-3]

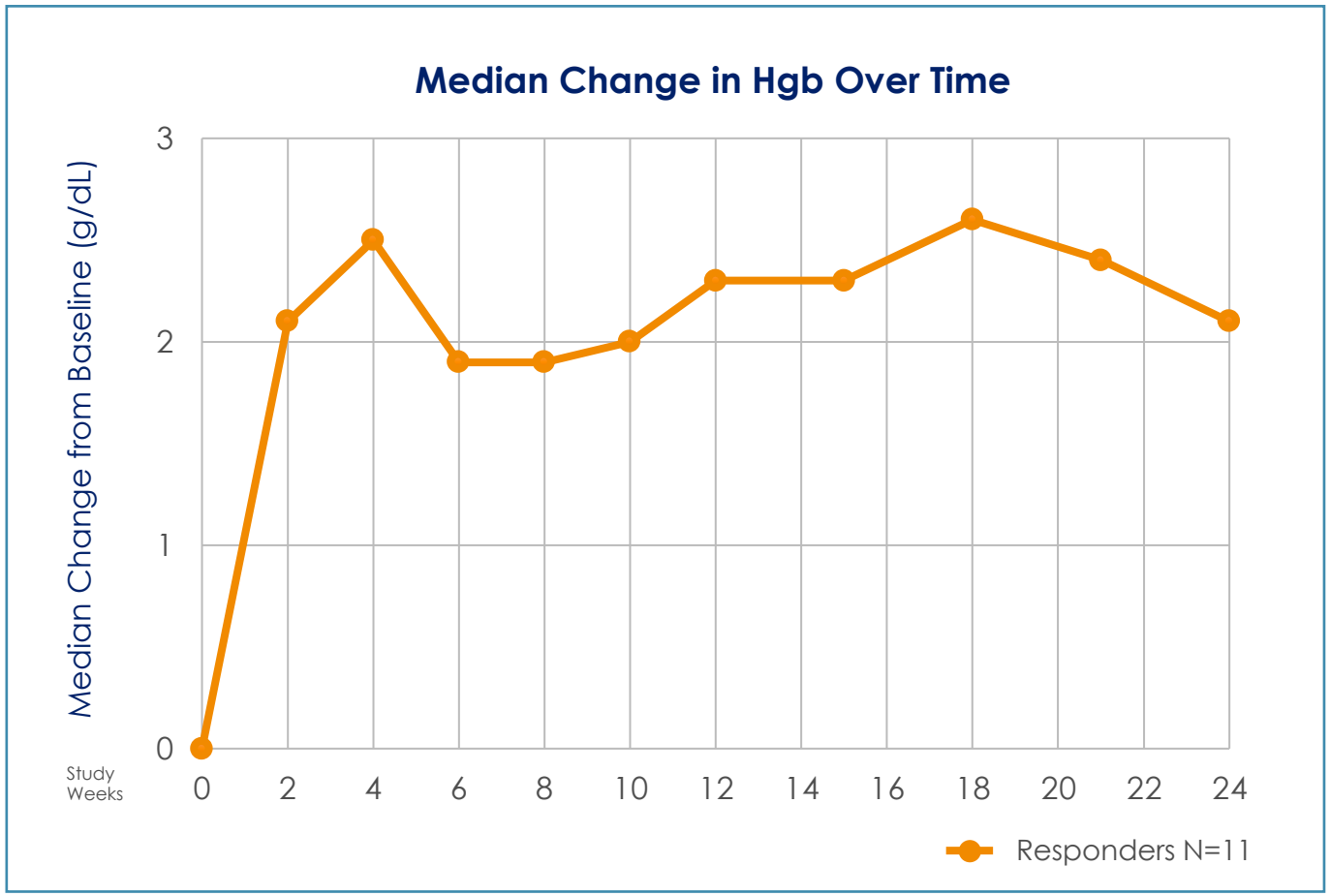


- In wAIHA, autoantibodies bind to protein antigens on red blood cells (RBC) at body temperature, leading to RBC phagocytosis and destruction by Fcγ receptor-bearing macrophages in a spleen tyrosine kinase (SYK) dependent signaling pathway
- Fostamatinib prevents RBC phagocytosis by macrophages and blocks B-cell activation and differentiation into plasma cells that secrete autoantibodies.[4,5]
- In animal studies, fostamatinib prevented antibody-induced anemia[6]
- No evidence of immunosuppression by fostamatinib

LYN: Lck/yes novel protein kinase; MHC, major histocompatibility complex; RBC, red blood cell; SYK: spleen tyrosine kinase; TCR, t cell receptor; Th, t helper.

1. Cooper N, et al. *Blood*. 2020;136(Suppl 1):1–3. 2. European Hematology Association 2018 Rigel AIHA Presentation. 3. Data on file, Rigel Pharmaceuticals, Inc. December 2021. 4. Davidzohn N., et al. *J Exp Med*. 2020;217(3). 5. Roders, et al., *Front Immunol*. 2018;9:787. 6. Podolanczuk A., Blood.2009;113(14:3154-3160.

wAIHA Phase 2 Clinical Trial Results



11 of 24 (46%)

patients responded by Week 24 plus 1 late responder at Week 30 (total of 12 responders = 50%)

- Response = Hgb >10 g/dL with an increase of ≥2 g/dL from baseline without rescue therapy or RBC transfusion

7 of 24 (29%)

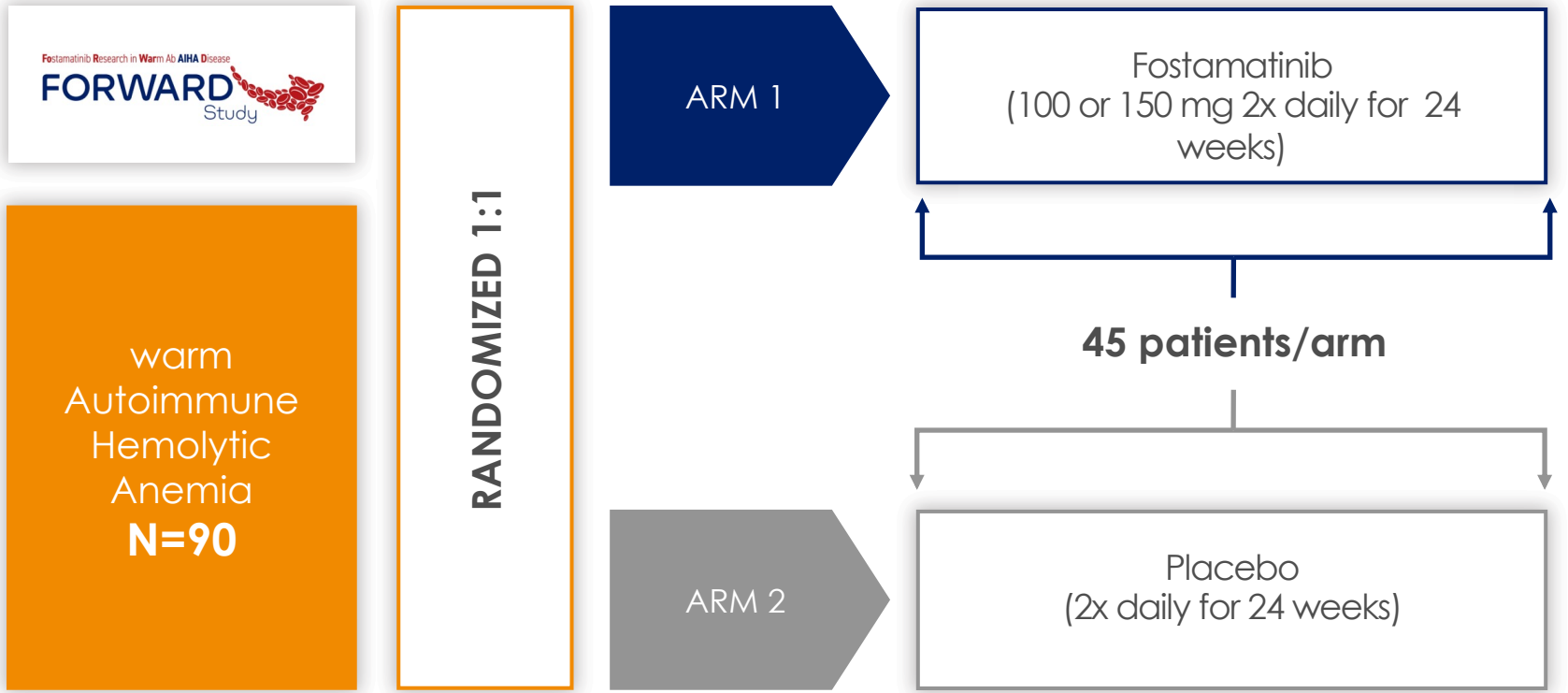
patients achieved a durable response of 3 consecutive visits with Hgb ≥10 and ≥+2 by Week 24

Increases in median Hgb were generally detected at Week 2 (first visit) and sustained over time

Safety profile is consistent with the fostamatinib safety database of >4800 patients across all disease programs

Kuter, D., et al. (2022). Fostamatinib for the treatment of warm antibody autoimmune hemolytic anemia: Phase 2, multicenter, open-label study . *Am J Hematol.* In press https://doi.org/10.1002/ajh.26508

Enrollment Complete for wAIHA Phase 3 Clinical Trial



Concurrent wAIHA therapies* (max 2) allowed during initial 24-week study period

Reduction in steroids allowed at 12 weeks in patients with Hgb response (following steroid taper protocol)

Primary Endpoints:

- Hgb ≥ 10 g/dL with an increase of ≥ 2 g/dL from baseline on 3 consecutive available visits

Secondary Endpoints:

- Hemoglobin response on ≥1 visit
- Hemoglobin response of ≥ 2 g/dL from baseline
- Change in hemoglobin value from baseline to end of study
- Use of rescue medication

*steroids, azathioprine, erythropoiesis-stimulating agents, mycophenolate mofetil, dapsone, danazol

Nichola Cooper, Robert P. Numerof, Sandra Tong, David J. Kuter; Fostamatinib for the Treatment of Warm Antibody Autoimmune Hemolytic Anemia (wAIHA): A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Global Study. *Blood* 2020; 136 (Supplement 1): 1–3. doi: https://doi.org/10.1182/blood-2020-140469

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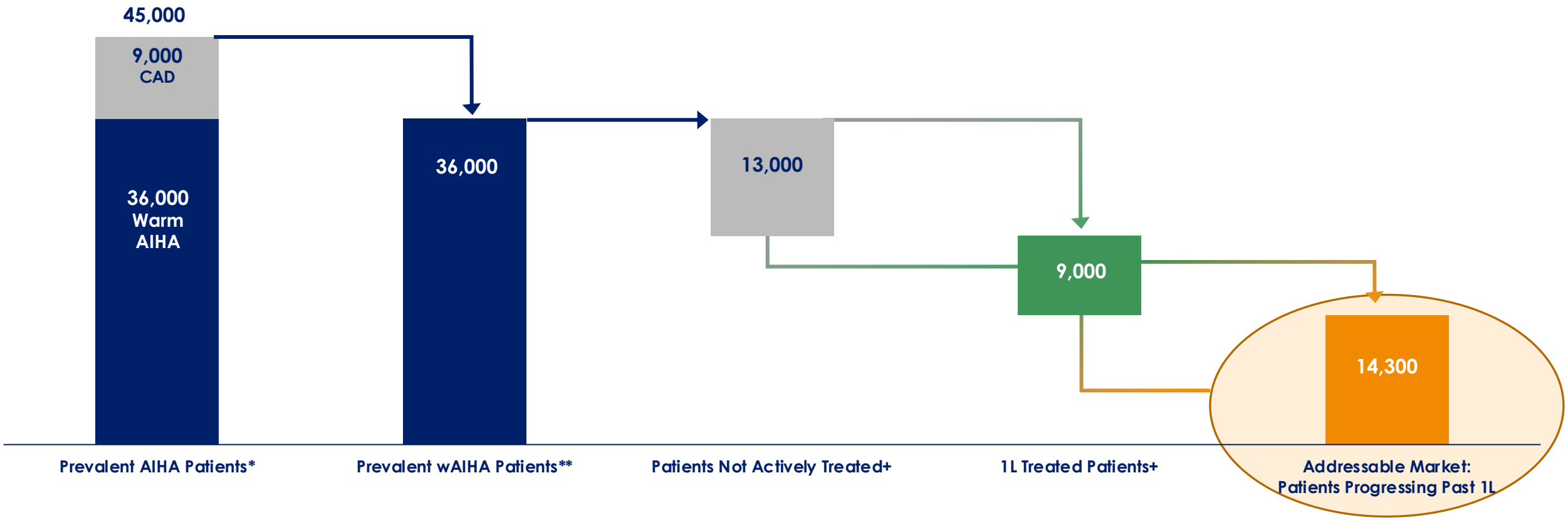
Potential Commercial Opportunity for wAIHA

Attractive Market Opportunity of Addressable Patients

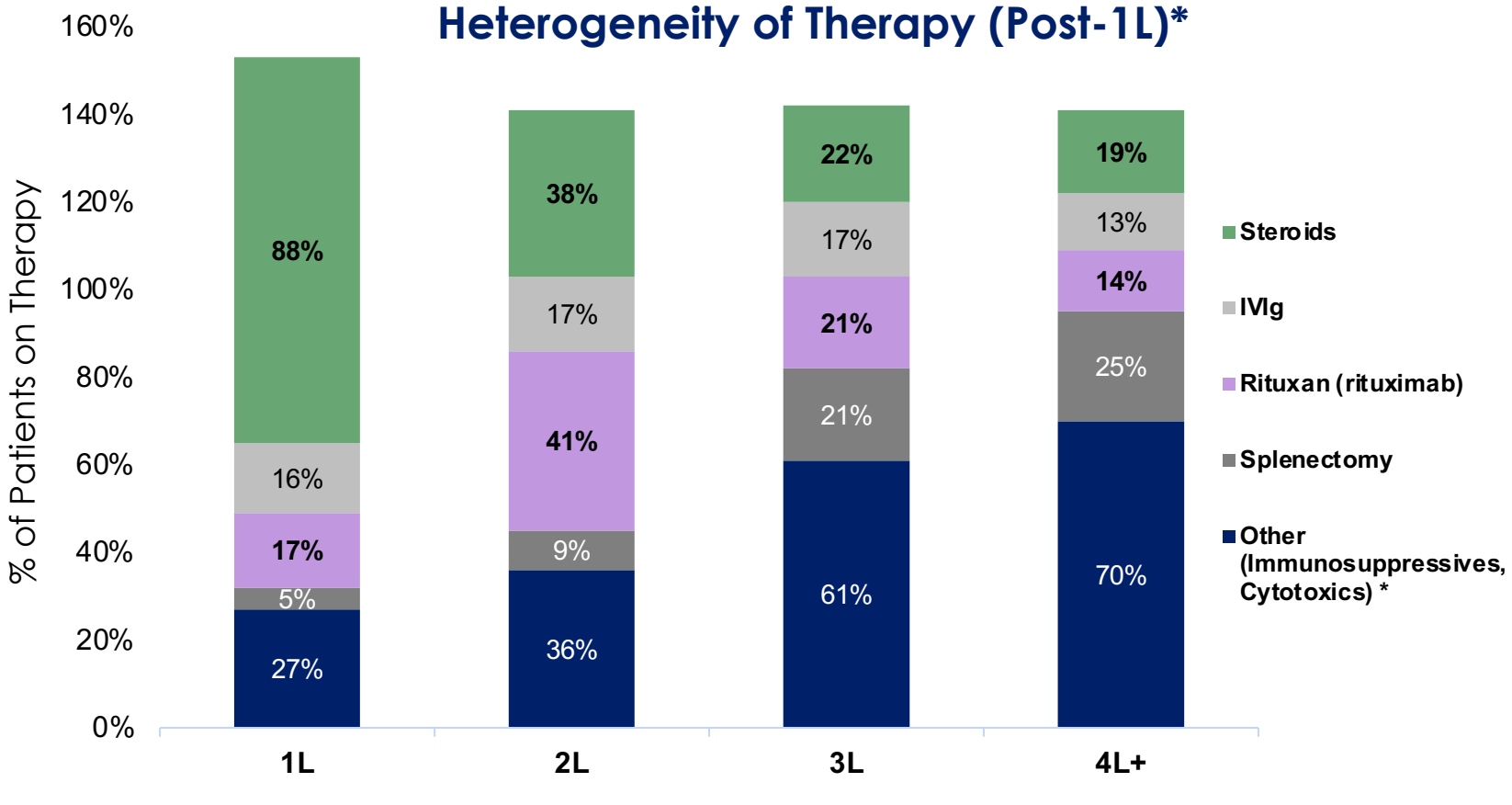


wAIHA patients will move into and out of active treatment over time

Sources: * Prevalence: A. Zanella, et al, , haematologica | 2014; 99(10) | CAD = Cold Agglutinin Disease
** % Warm AIHA: T. Kalfa; Hematology Am Soc Hematol Educ Program. 2016 Dec 2; 2016(1): 690–697
+ Quantitative Physician Research, May 2021, n = 150;

Significant Unmet Need in Complex Prescribing Landscape

- **No approved** wAIHA targeted therapies
- **Mix and match** treatment approach
- Patients **cycling on and off treatment** and **in between treatments**
- Certain treatments are **burdensome on patients**



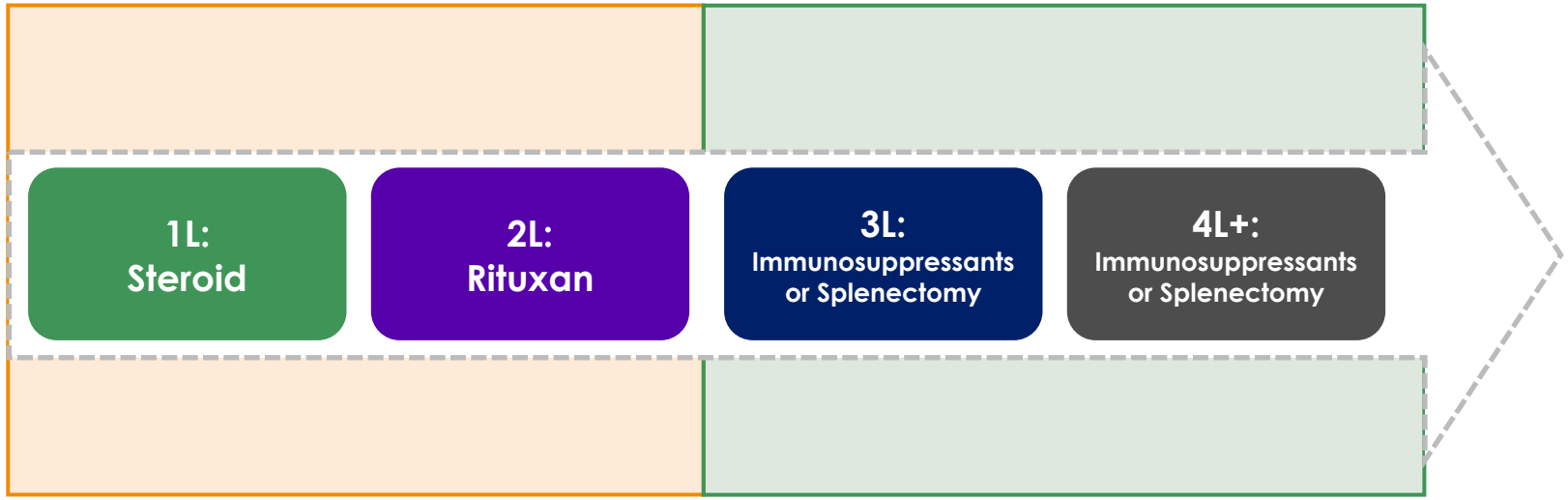
TAVALISSE has the potential to significantly reduce treatment burden with a tolerable side effect profile

Source: Quantitative Physician Research, May 2021, n = 150
*Most commonly mentioned "Other" therapies include Cytoxan (cyclophosphamide), Imuran (azathioprine), Cellcept (mycophenolate mofetil) and Danazol

Unmet Needs Lead to Both Opportunities and Challenges with Launch Planning

Lower Perceived Unmet Need (1L & 2L)

Higher Perceived Unmet Need 3L+



Research Insights

- Peak share likely achieved over several years due to diffusion of patients and habituation of HCPs with current treatment options
- Current therapies are used intermittently
- Current literature is not definitive on how to manage AIHA chronically

Launch Opportunities and Challenges

- Driving awareness and appropriate patient identification key to launch success
- Universal acceptance of unmet need in 3rd line and beyond
- Large opportunity to elevate the value of a targeted agent, used chronically, earlier in the treatment paradigm

Source: Qualitative Research, November 2020, n=30 | Quantitative Physician Research, May 2021, n = 150

Grow Global Sales of TAVALISSE® in ITP

Tavalisse®
(fostamatinib disodium hexahydrate) tablets

Kinase inhibitor indicated for the treatment of thrombocytopenia in adult patients with chronic immune thrombocytopenia (cITP) who have had an insufficient response to a previous treatment.

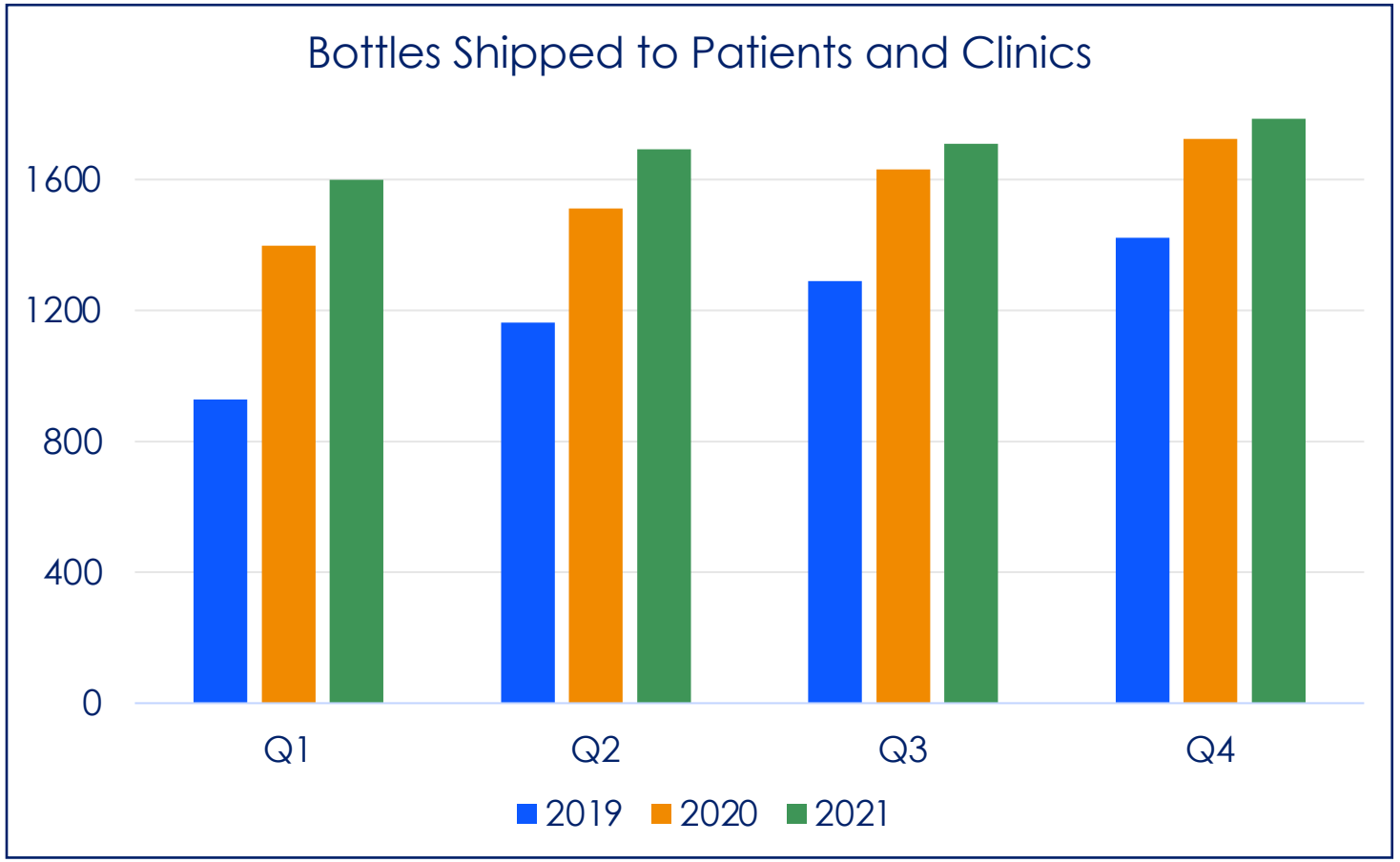
Select Important Safety Information

Adverse Reactions

- Serious adverse drug reactions in the ITP double-blind studies were febrile neutropenia, diarrhea, pneumonia, and hypertensive crisis, which occurred in 1% of TAVALISSE patients. In addition, severe adverse reactions occurred including dyspnea and hypertension (both 2%), neutropenia, arthralgia, chest pain, diarrhea, dizziness, nephrolithiasis, pain in extremity, toothache, syncope, and hypoxia (all 1%).
- Common adverse reactions (≥5% and more common than placebo) from FIT-1 and FIT-2 included: diarrhea, hypertension, nausea, dizziness, ALT and AST increased, respiratory infection, rash, abdominal pain, fatigue, chest pain, and neutropenia.

Please see slides 36 & 37 for Important Safety Information. Please visit www.TAVALISSE.com for full prescribing information.

TAVALISSE 2021 Performance



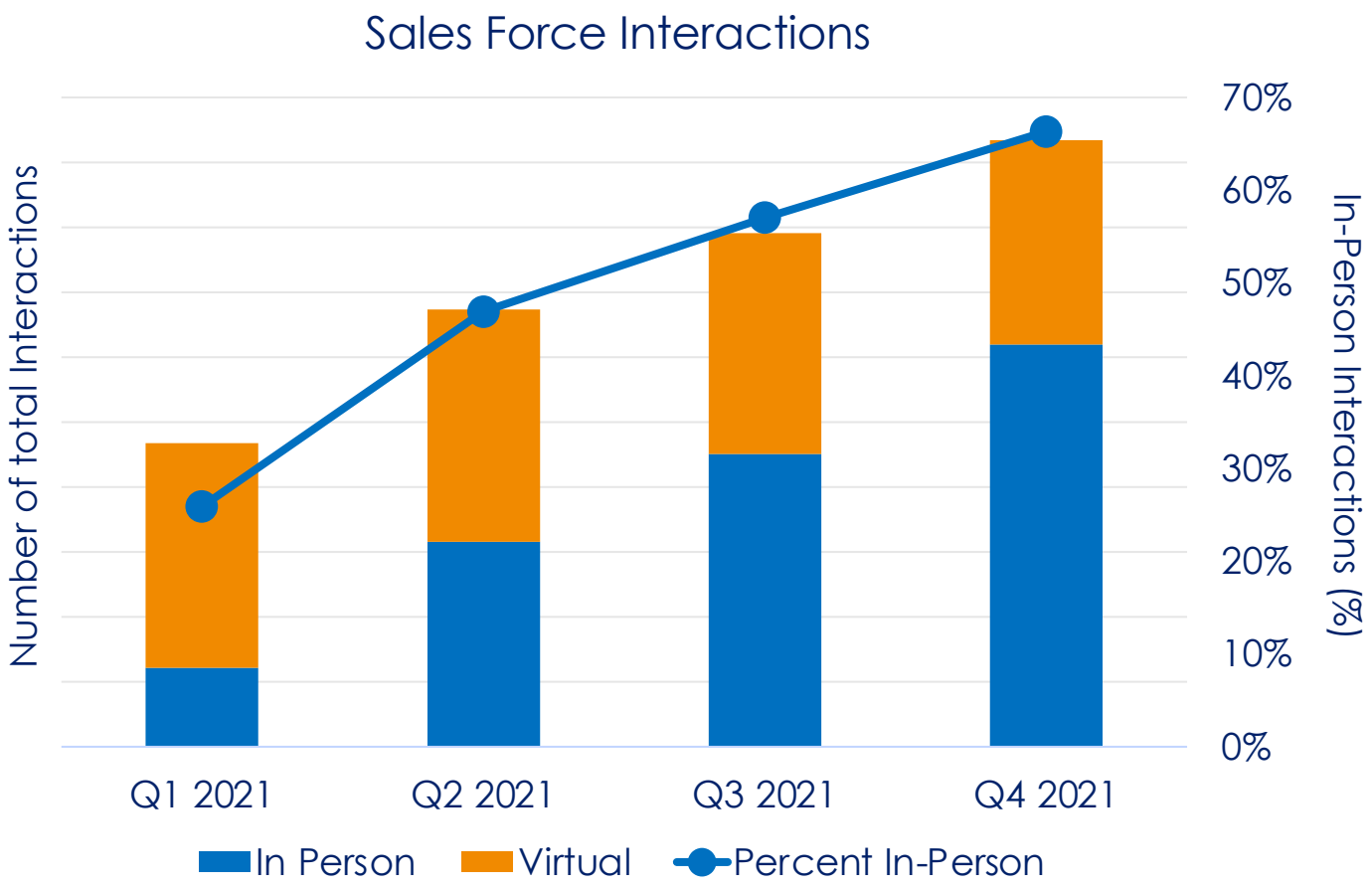
2021 Quarterly Results

$17.6M Q4 net product sales

Highest Bottles Shipped to Patients and Clinics since Launch:

8% Annual Growth over 2020

Customer Interactions Reached the Highest Level of 2021



Q4 2021 Interactions Trend

37% **More In-person interactions vs. Q3 '21**

Strong growth resulting from Sales Force Expansion

In-Person Interactions have grown to

~65% **of total interactions**

In Person Speaker Programs also reached the highest level of the year in Q4

Key Brand and Market Access Initiatives

American Society of Hematology Annual Meeting and Exposition

- Strong Rigel and Tavalisse presence
- Customers happy to connect in-person
- Preference to engage in-person rather than virtually

Tavalisse is now Preferred on Key 2022 Commercial National Formularies

- Significant increase in National Commercial Coverage
- Reinforces Tavalisse's proven efficacy and safety
- Strengthens Reimbursement Confidence
- Spreading awareness among customers through personal and non-personal channels
- Already seeing positive impact as more patients move to commercial coverage

[1]Company's internal estimate based on 2018 sales of ITP therapies used for steroid-refractory patients.

Explore TAVALISSE in COVID-19 & Beyond

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Seeking to Make a Difference in COVID-19

Compelling scientific rationale supported by **external research**

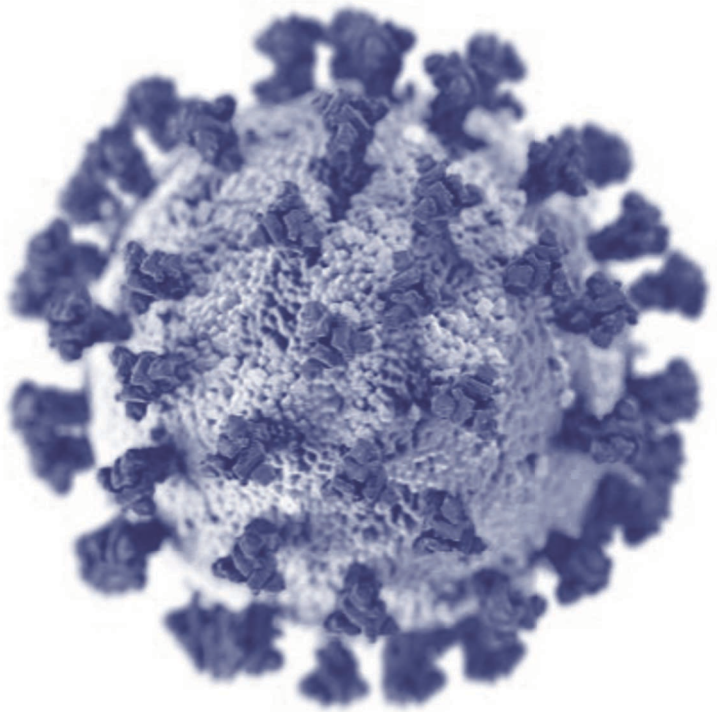
Positive readout for NIH/NHLBI-sponsored Phase 2 trial in hospitalized patients with COVID-19

Three ongoing clinical studies:

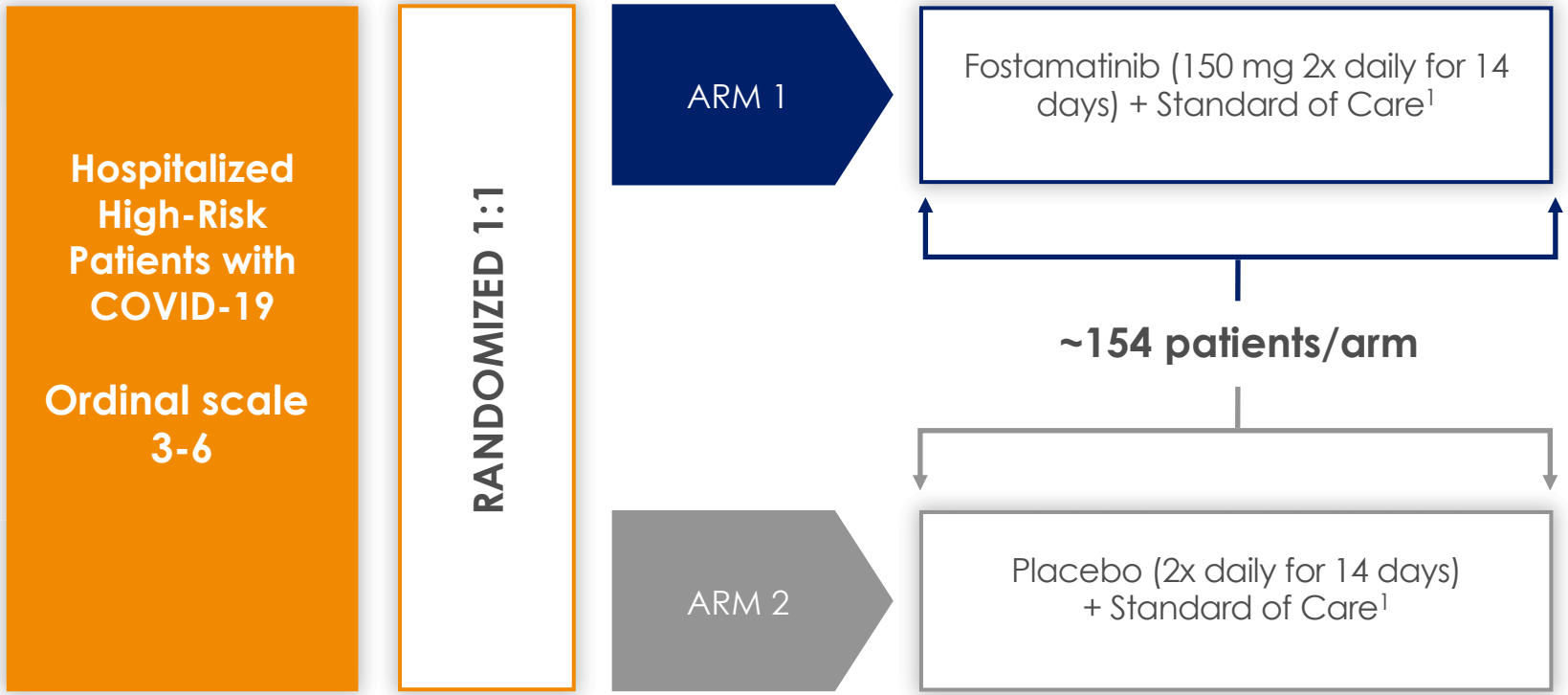
- Rigel-led Phase 3 clinical trial
- NIH/NHLBI-sponsored ACTIV-4 Host Tissue Phase 3 clinical trial
- Imperial College London sponsored Phase 2 clinical trial

Need for therapeutics expected to persist even with vaccines

Commercial availability could enable quick access and adoption



Rigel Phase 3 Clinical Trial



New Primary Endpoint:

- Number of days on oxygen through day 29
- Expanded patient population to include patients with more severe disease

Secondary Endpoints:

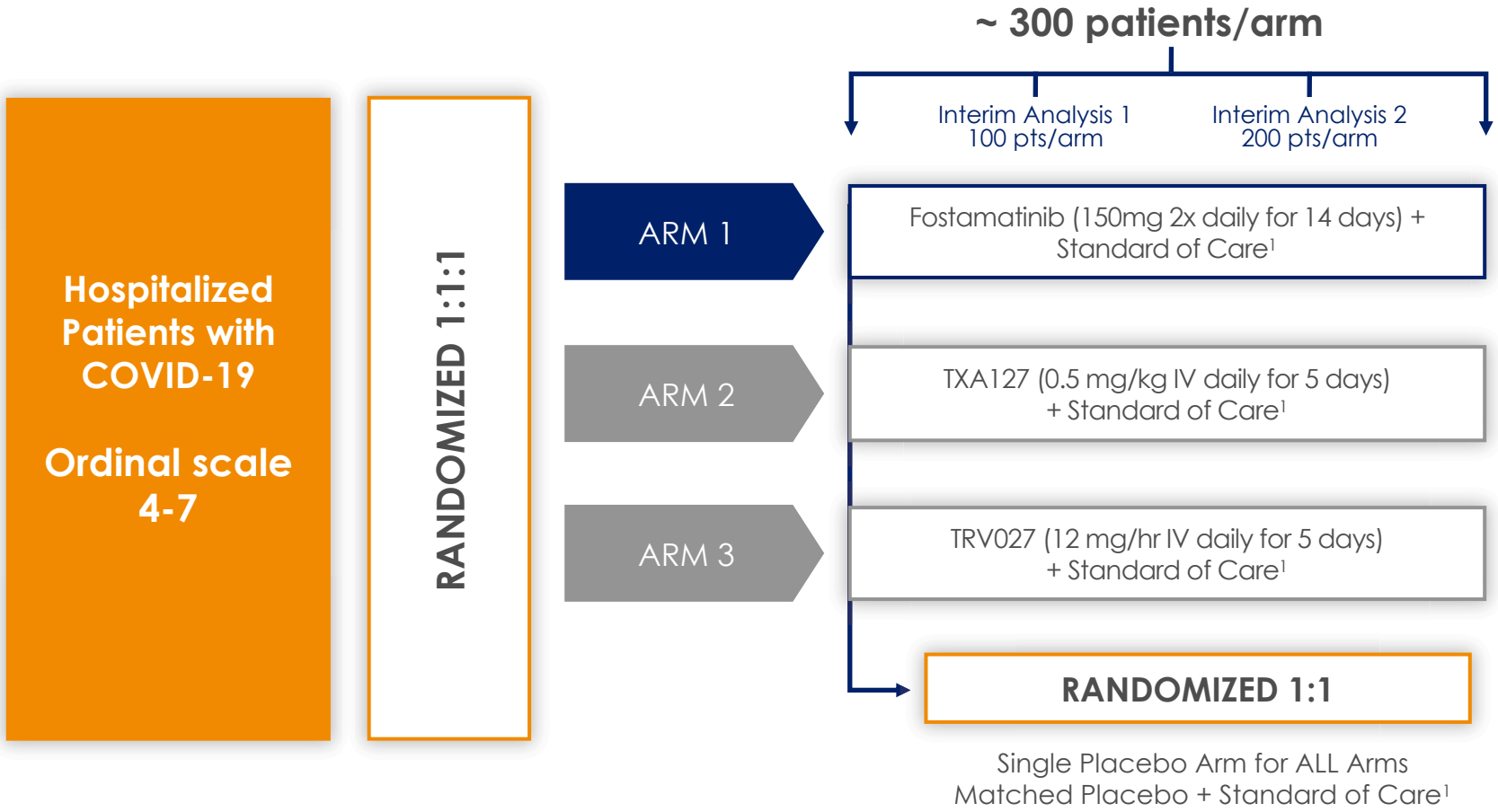
- Multiple secondary measures designed to assess mortality risk, patient improvement from severe disease and duration of hospitalization

Enrollment:

- 265 patients enrolled as of February 28, 2022

[1]Standard of care includes any treatments currently in use to treat the underlying disease, or comorbidities associated with COVID-19 (eg, remdesivir).

ACTIV-4 Host Tissue Phase 3 Clinical Trial Design



Primary Endpoints:

- Oxygen free days through day 28

Secondary Endpoints:

- Multiple secondary measures include hospital mortality, use of mechanical ventilation, and WHO scale scores

[1]Standard of care includes any treatments currently in use to treat the underlying disease, or comorbidities associated with COVID-19 (eg, remdesivir).

Advance Pipeline Programs

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Targeting IRAK1 & IRAK4 Pathways in Inflammatory Disease

R289/835[1] is a dual inhibitor of both IRAK1 and IRAK4 pathways

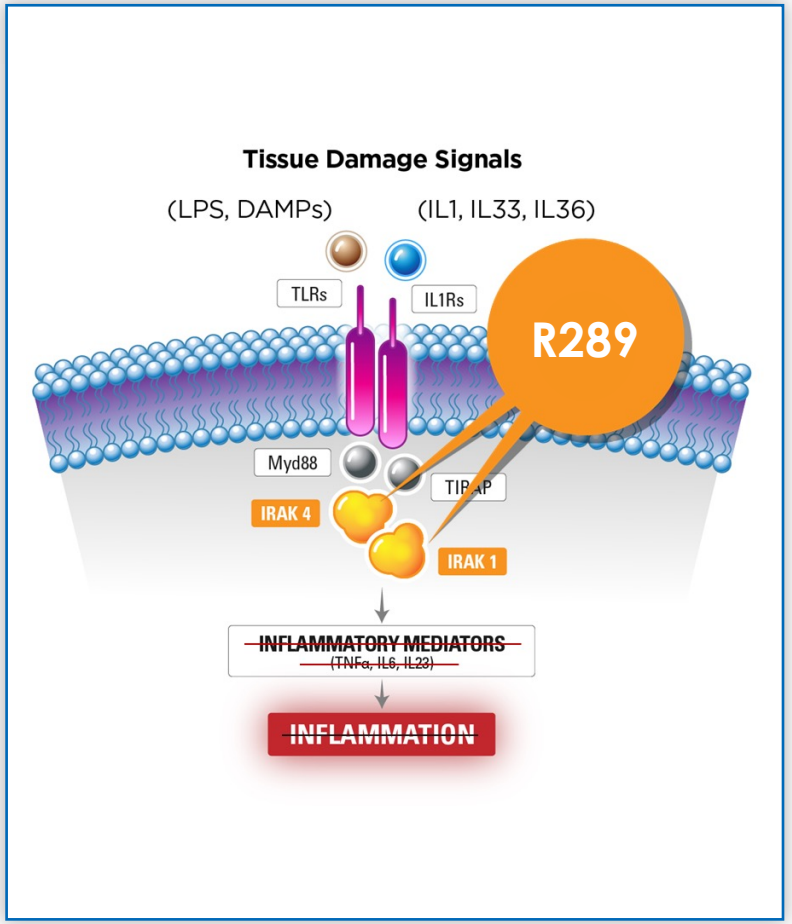
- Inhibition of IRAK1/4 kinases has therapeutic potential for multiple inflammatory and autoimmune diseases
- In a preclinical study, dual Inhibition of IRAK1 & IRAK4 with R835 demonstrated stronger suppression of inflammatory cytokines compared to an IRAK4-selective inhibitor[2]

Attractive opportunities in heme/onc and rare immune diseases align with development strategy

- Low-risk MDS: targeting the IRAK1 and 4 pathways, through inhibition, has the potential to alleviate the bone marrow deficiency and cytopenias in myelodysplastic syndromes
- Activation of innate immune system through TLRs and IL-1Rs plays an important role in MDS pathogenesis
- The downstream IRAK1/4 signaling network mediates NLRP3 inflammasome-driven pyroptosis, which drives bone marrow inflammation in low-risk MDS
- Phase 1b study in low-risk MDS now underway

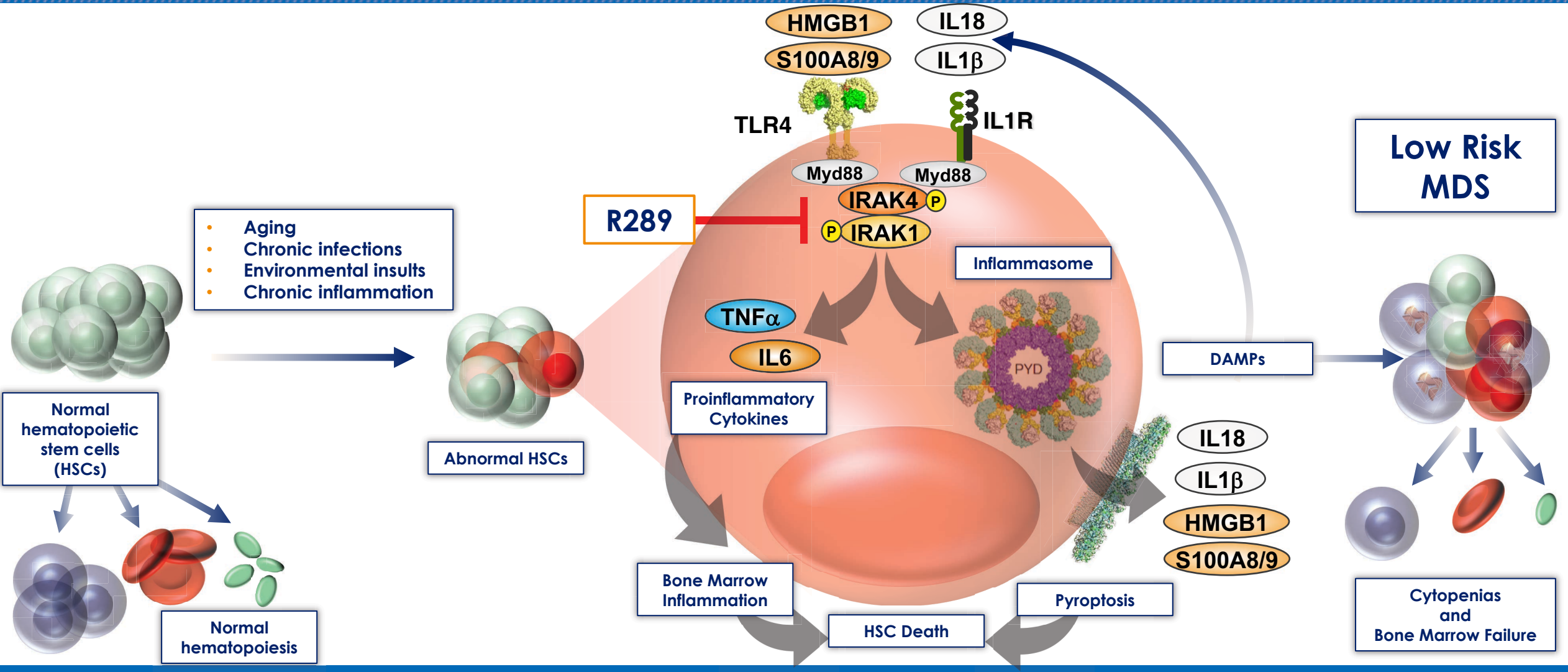
Next Steps:

- Exploring indications in rare autoimmune diseases



[1]R289/R835 is an investigational compounds not approved by the FDA. [2]Rigel data on file.

Bone Marrow Failure in LRMDS is Driven by Chronic Inflammation and Pyroptosis of Normal Hematopoietic Stem Cells (HSCs)[1-3]



[1]Sallman, DA, Front Oncol. 2016;6:151. 2. Monlish DA, *Front Immunol*. 2016;7:390. 3. Barreyro L, *Blood*. 2018;132(15):1553-60.

Low Risk MDS Treatment Landscape

- MDS is a clonal disorder of hematopoietic stem cells (HSCs) leading to dysplasia and ineffective hematopoiesis in the bone marrow
- Risk of autoimmune abnormalities, cytopenia (RBC, platelets, WBC), progression to acute myeloid leukemia (AML) and death

1

First-Line Therapy Transfusions and ESAs

Treatment of symptomatic low-risk MDS includes frequent blood transfusions and Erythropoiesis-Stimulating Agents (ESAs) for anemia

2

Second-Line Therapy Lenalidomide, Luspatercept and HMAs

Lenalidomide, luspatercept, hypomethylating agents (HMAs), and immunosuppressive therapy provide limited hematologic response in selected subsets of patients, durable responses are not common, and these agents can result in significant adverse effects

X

Loss of Response

to HMAs in patients with lower-risk disease is associated with an overall survival of only 12 to 14 months and significant morbidity associated with cytopenias[1]

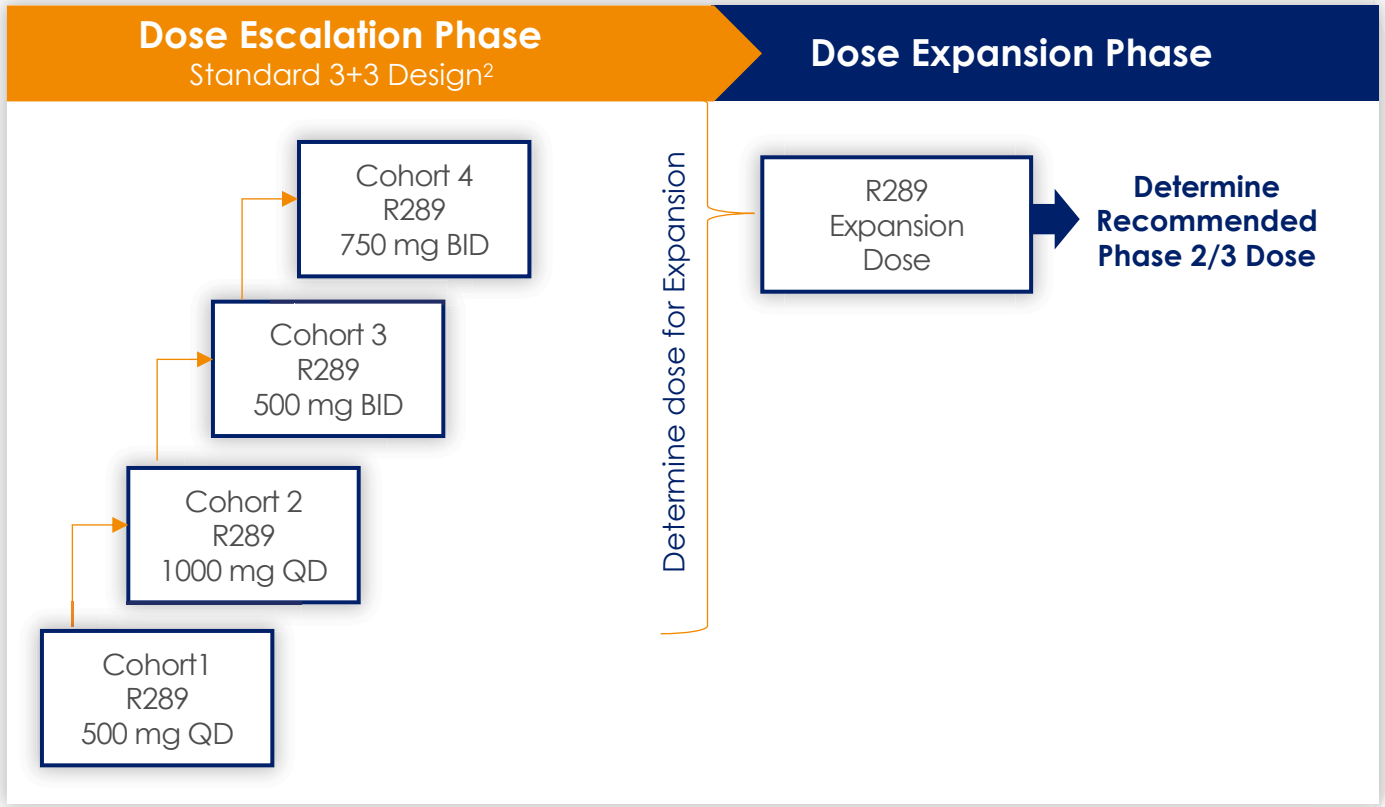
There are currently no standard therapies for low risk MDS patients who are refractory/resistant to current therapies such as ESAs or HMAs

1. Jabbour E, Garcia-Manero G, Batty N. et al. Outcome of patients with myelodysplastic syndrome after failure of decitabine therapy. *Cancer*. 2010, 116(16): 3830-3834.

Open-label Phase 1b Study of R289[1] in Patients with Low Risk MDS

Patients with Low Risk MDS

Relapsed/Refractory or Inadequate Response to Prior Therapy with Known Clinical Benefit*



Primary Endpoint:

- Safety

Secondary Endpoints:

- Preliminary Efficacy
  - Transfusion independence
  - Remission
  - Overall response
  - Hematologic Improvement
- PK
- Biomarkers

*Thrombopoietin (TPO), erythropoietin (EPA), luspatercept, and HMAs (i.e., azacytidine or decitabine). Patients with del (5q) must have failed prior lenalidomide therapy.

[1]R289 is an investigational compound not approved by the FDA. 2. Jaki T, Clive S, Weir CJ. Principles of dose finding studies in cancer: a comparison of trial designs. *Cancer Chemother Pharmacol*. 2013; 71(5): 1107-1114. doi:10.1007/s00280-012-2059-8

Advancing RIPK1 Inhibitor Program with Partner Lilly

Comprehensive RIPK1 Inhibitor Program:

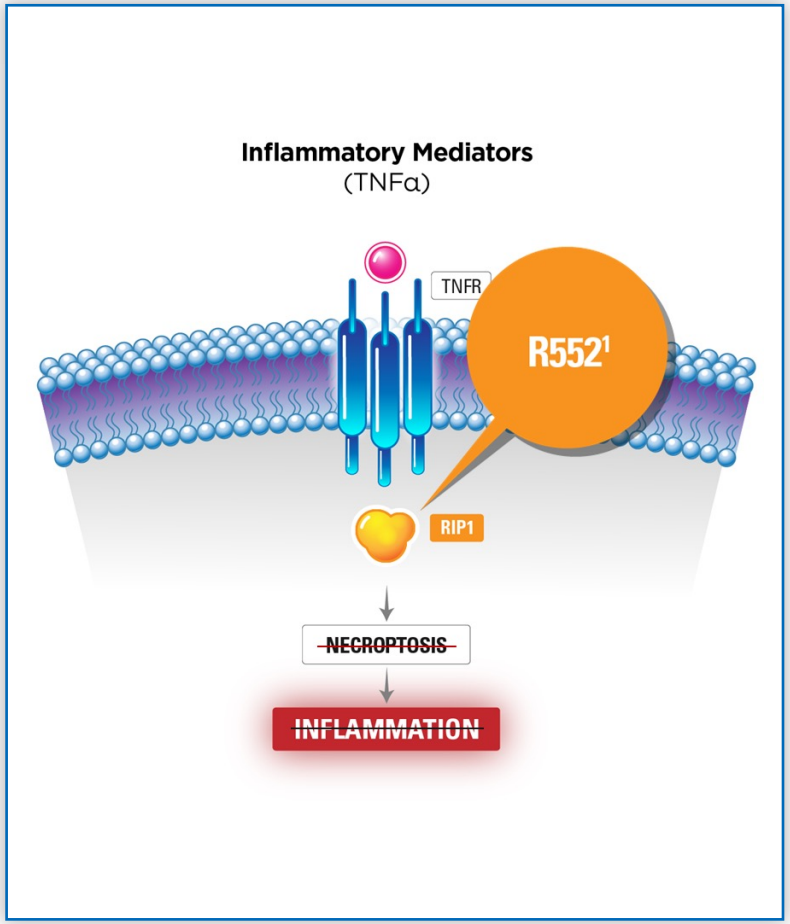
R552, a potent and selective RIPK1 inhibitor, completed Phase 1 study which demonstrated potential best-in-class status compared to competition

- Rigel and Lilly currently planning the first Phase 2 study in psoriasis to begin 1H 2022

Selection of RIPK1 inhibitor candidates that cross the blood-brain barrier for CNS diseases is underway

- Lilly would lead clinical development of brain-penetrating RIPK1 inhibitors in CNS diseases

RIPK1 inhibitors play key role in TNF signaling and induction of pro-inflammatory necroptosis, which could support broad potential in psoriasis, RA and IBD, and with their expertise and experience, Lilly is the ideal partner



[1]R552 is an investigational compound not approved by the FDA.

Financials

Q4 & YE 2021 Financial Highlights

Net product sales:

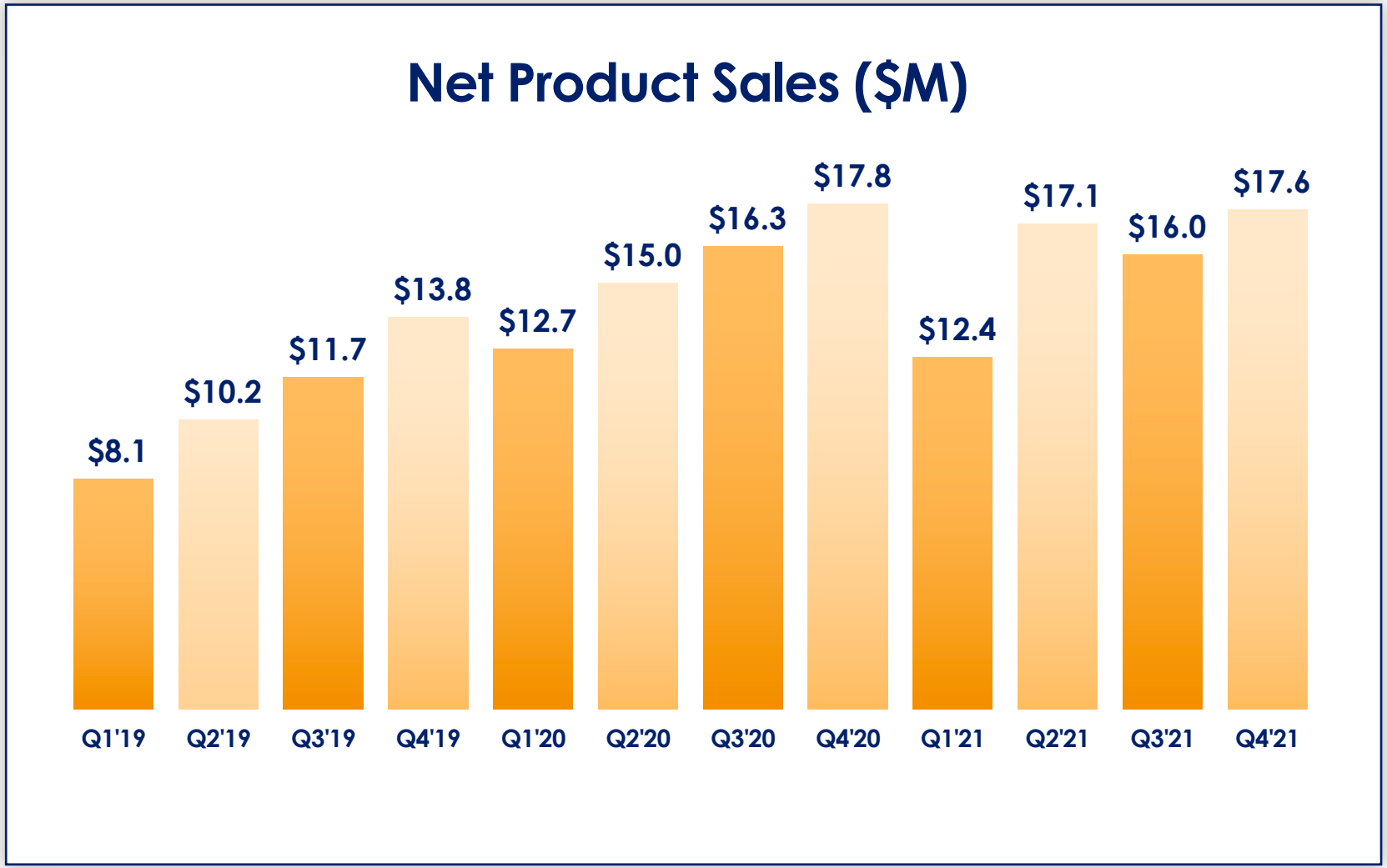
- $17.6M in Q4 '21
- $63.0M in FY '21
- $182.6M since launch

Total Bottles shipped:

- 1,814 in Q4 '21
- 6,740 in FY '21

Q4 '21 Bottles:

- 1,785 bottles shipped to patients & clinics
- 29 bottle increase in distribution channels[1]



[1] 937 total bottles remained in distribution channels as of December 31, 2021

Q4 &YE 2021 Financial Results

(In thousands, except for per share amounts)

	Three Months Ended December 31,		Year Ended December 31,	
	2021	2020	2021	2020
Revenues				
Net Product Sales	$ 17,569	$ 17,753	$ 63,010	$ 61,696
Contract revenues from collaborations	1,840	697	75,726	46,925
Government contract	1,000	-	10,500	-
Total revenues	20,409	18,450	149,236	108,621
Costs and expenses:				
Cost of product sales	487	321	1,083	895
Research and development	13,304	15,138	65,237	60,101
Selling, general and administrative	24,515	21,818	91,891	76,598
Restructuring charges	3,521	-	3,521	-
Total costs and expenses	41,827	37,277	161,732	137,594
Loss from operations	(21,418)	(18,827)	(12,496)	(28,973)
Interest income	16	19	47	582
Interest expense	(1,299)	(429)	(4,860)	(1,353)
Benefit from (Provision for) income taxes	60	-	(605)	-
Net loss	$ (22,641)	$ (19,237)	$ (17,914)	$ (29,744)
Net loss per share, basic and diluted	$ (0.13)	$ (0.11)	$ (0.11)	$ (0.18)
Weighted average shares used in computing loss per share, basic and diluted	171,071	169,039	170,492	168,754

- In Q4 2021, contract revenues from collaborations of **$1.8M:**
  - **$0.2M** Lilly license agreement
  - **$1.3M** Grifols collaboration agreement
  - **$0.3M** Kissei collaboration agreement
- In Q4 2021, government contract revenue of **$1.0M** was related to U.S. DOD support for Rigel's ongoing Phase 3 clinical trial of fostamatinib in hospitalized COVID-19 patients
- Cash, cash equivalents & short-term investment balance totaled **$125.0M** as of December 31, 2021

Please see slides 36 & 37 for Important Safety Information. Please visit www.TAVALISSE.com for full prescribing information.

Catalysts Anticipated Throughout 2022

Grow Sales in ITP

Accelerate TAVALISSE sales with expanded sales force and increased interactions as pandemic conditions normalize

Continue to educate on the benefits of early-line use and 5-year durability

Support existing collaborations to expand global access

>$2B[2]

Capitalize on wAIHA[1] Opportunity

Phase 3 FORWARD study topline data expected mid-2022

Submit regulatory filings in 2022 if data is positive

Potential $1B US[3]

Explore Fostamatinib in COVID-19[1] & Beyond

Complete enrollment and generate results of the Rigel Phase 3 clinical trial

Submit EUA if data is positive

>$2B[4]

Advance Pipeline Programs

Initiate R289 Phase 1b study in low-risk MDS in Q1 2022

Advance IRAK1/4 program in rare immune diseases

Lilly to initiate R552 Phase 2 study in psoriasis

Deliver CNS-penetrant RIPK1 molecule to Lilly for clinical development

Substantial

MARKET OPPORTUNITY

[1]Investigational compound in this indication and has not been submitted for FDA review. [2]Company's internal estimate based on 2018 sales of ITP therapies used for steroid-refractory patients. [3]DelveInsight Research "Warm Autoimmune Hemolytic Anemia [wAIHA] – Market Insight, Epidemiology, and Market Forecast". [4]Johns Hopkins University COVID-19 Tracker, COVID Tracking Project, IntegriChain 852 and 867 and HHS admissions.
Please see slides 36 & 37 for Important Safety Information. Please visit www.TAVALISSE.com for full prescribing information.

TAVALISSE® (fostamatinib disodium hexahydrate) Tablets

Indication and Important Safety Information

Indication

TAVALISSE® (fostamatinib disodium hexahydrate) tablets is indicated for the treatment of thrombocytopenia in adult patients with chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment.

Important Safety Information I Warnings and Precautions

- Hypertension can occur with TAVALISSE treatment. Patients with pre-existing hypertension may be more susceptible to the hypertensive effects. Monitor blood pressure every 2 weeks until stable, then monthly, and adjust or initiate antihypertensive therapy for blood pressure control maintenance during therapy. If increased blood pressure persists, TAVALISSE interruption, reduction, or discontinuation may be required.
- Elevated liver function tests (LFTs), mainly ALT and AST, can occur with TAVALISSE. Monitor LFTs monthly during treatment. If ALT or AST increase to >3 x upper limit of normal, manage hepatotoxicity using TAVALISSE interruption, reduction, or discontinuation.
- Diarrhea occurred in 31% of patients and severe diarrhea occurred in 1% of patients treated with TAVALISSE. Monitor patients for the development of diarrhea and manage using supportive care measures early after the onset of symptoms. If diarrhea becomes severe (≥Grade 3), interrupt, reduce dose or discontinue TAVALISSE.
- Neutropenia occurred in 6% of patients treated with TAVALISSE; febrile neutropenia occurred in 1% of patients. Monitor the ANC monthly and for infection during treatment. Manage toxicity with TAVALISSE interruption, reduction, or discontinuation.
- TAVALISSE can cause fetal harm when administered to pregnant women. Advise pregnant women the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment and for at least 1 month after the last dose. Verify pregnancy status prior to initiating TAVALISSE. It is unknown if TAVALISSE or its metabolite is present in human milk. Because of the potential for serious adverse reactions in a breastfed child, advise a lactating woman not to breastfeed during TAVALISSE treatment and for at least 1 month after the last dose.

TAVALISSE® (fostamatinib disodium hexahydrate) Tablets

Important Safety Information (cont.)

Drug Interactions

- Concomitant use of TAVALISSE with strong CYP3A4 inhibitors increases exposure to the major active metabolite of TAVALISSE (R406), which may increase the risk of adverse reactions. Monitor for toxicities that may require a reduction in TAVALISSE dose.
- It is not recommended to use TAVALISSE with strong CYP3A4 inducers, as concomitant use reduces exposure to R406.
- Concomitant use of TAVALISSE may increase concentrations of some CYP3A4 substrate drugs and may require a dose reduction of the CYP3A4 substrate drug.
- Concomitant use of TAVALISSE may increase concentrations of BCRP substrate drugs (eg, rosuvastatin) and P-Glycoprotein (P-gp) substrate drugs (eg, digoxin), which may require a dose reduction of the BCRP and P-gp substrate drug.

Adverse Reactions

- Serious adverse drug reactions in the ITP double-blind studies were febrile neutropenia, diarrhea, pneumonia, and hypertensive crisis, which occurred in 1% of TAVALISSE patients. In addition, severe adverse reactions occurred including dyspnea and hypertension (both 2%), neutropenia, arthralgia, chest pain, diarrhea, dizziness, nephrolithiasis, pain in extremity, toothache, syncope, and hypoxia (all 1%).
- Common adverse reactions (≥5% and more common than placebo) from FIT-1 and FIT-2 included: diarrhea, hypertension, nausea, dizziness, ALT and AST increased, respiratory infection, rash, abdominal pain, fatigue, chest pain, and neutropenia.

Please see http://www.tavalisse.com/ for full Prescribing Information

To report side effects of prescription drugs to the FDA, visit http://www.fda.gov/medwatch or call 1-800-FDA-1088 (1-800-332-1088)

TAVA_ITP-22039

Thank you

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