

2024 Q1 results presentation and transcript

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Transcript

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Slide 1 – Sloan Simpson, Global Head of Investor Relations

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Q1 2024 Results

Investor presentation
April 23, 2024

 **NOVARTIS** | Reimagining Medicine

Good morning, and good afternoon, everyone. Thank you for joining our first quarter 2024 earnings call.

Slide 2 - Disclaimer

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Vas Narasimhan, M.D.
Chief Executive Officer



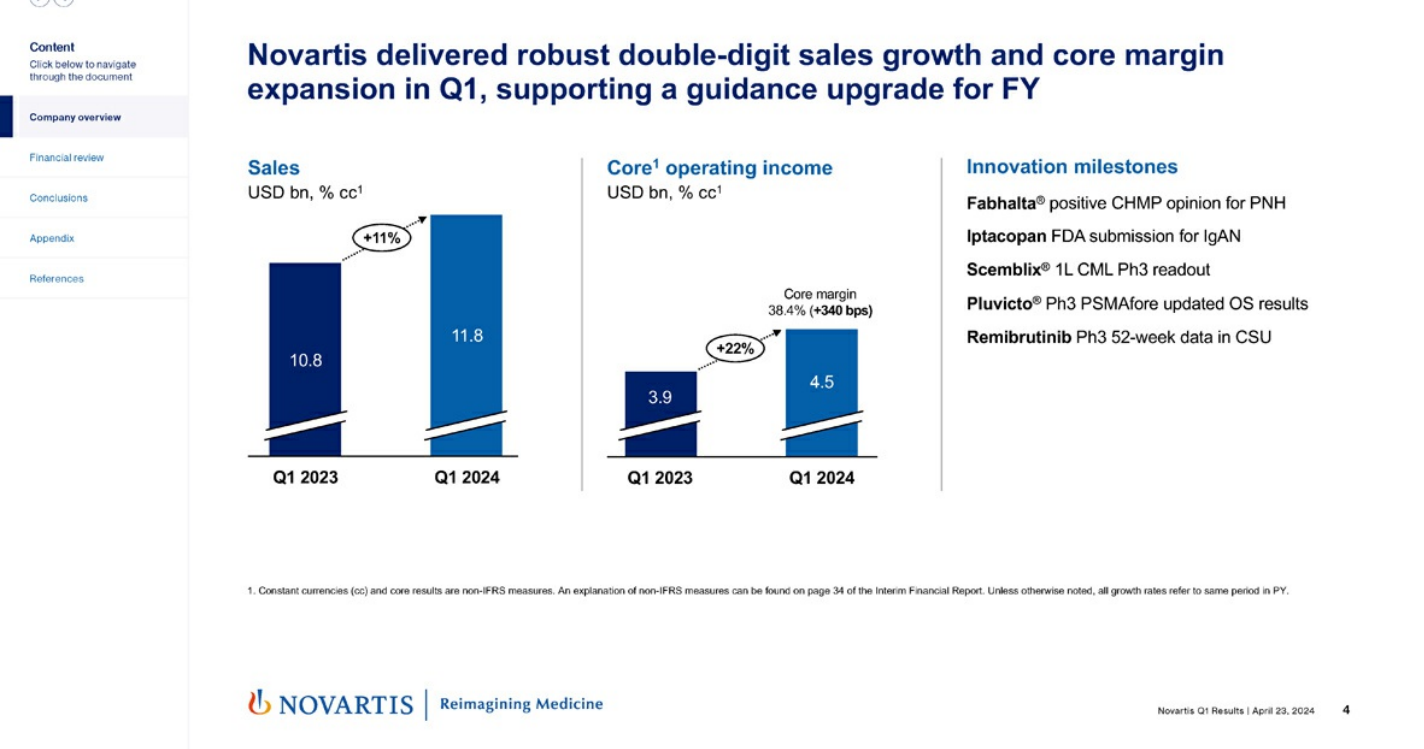
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Thank you, Sloan. I'd like to open today's call by first thanking Samir Shah for his incredible tenure as our Head of Investor Relations for over a decade. We're grateful for all of his contributions. We look forward to his

continued contributions in the new role at Novartis. And I want to welcome Sloan Simpson, I think Sloan will do an absolutely outstanding job serving all of you as our Head of Investor Relations. I've worked with Sloan for many, many years. I think we're really pleased and grateful to have her on board.

Slide 4

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So let's turn to the quarter. Novartis delivered a really strong start to the year with double-digit sales growth, core margin expansion, which enabled us to upgrade our guidance, and Harry will go through the guidance in more detail. Sales were up 11% in constant currency. Core operating income was up 22%. Our core margin reached 38.4% as we steadily march to our goal of 40% plus by 2027.

In addition, we had a number of important innovation milestones in the quarter, which I'll go through over the course of the call. But a few I'd want to particularly highlight, the Fabhalta® positive opinion enables us to launch Fabhalta® in Europe. Scemblix® first-line readout, we think will be very important for a major medicine for the company. And we also had the updated PSMAfore OS results, which will enable us now to move forward with the filing of Pluvicto® in the United States.

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Q1 sales

	Sales USD million	Growth vs. PY USD million	Growth vs. PY cc
Entresto	1,879	480	36%
Kesimpta	637	253	66%
Cosentyx	1,326	250	25%
KISQALI	627	212	54%
PLUVICTO	310	99	47%
LEQVIO	151	87	139%
SCENBLIX	136	60	83%
JAKAVI	478	64	18%
Xolair	399	45	15%
LUFTIS	356	28	14%
...	169	20	14%

Strong growth (+41% cc); expected to continue

Constant currencies (cc) is a non-IFRS measure. An explanation of non-IFRS measures can be found on page 34 of the Interim Financial Report. Unless otherwise noted, all growth rates refer to same period in PY.

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Now moving to Slide 5. Now our growth in the quarter was broad-based, and we had strong contributions from many of our key growth drivers, including Entresto®, Kesimpta®, Cosentyx®, which had a very strong quarter as well as Kisqali®. I would also say geographically, our performance was broad-based with strong growth across US, Europe, China with very strong growth and Japan.

As you can see on the chart, the strong growth was indicated by 41% constant currency growth, and we expect this growth to continue over the course of the year, which is what gives us confidence to do the upgraded guidance that we've outlined this morning.

Slide 6

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Entresto

Entresto® continued strong double-digit growth, +36% in Q1

Sales evolution

USD m, % cc

■ US ■ Ex-US

1,399

695

704

1,879

931

948

Q1 2023

Q1 2024

+36%

US weekly TRx¹

Total prescriptions (000)

80

70

60

50

40

30

20

10

0

July 2015

Mar 2024

Maintains strong momentum

• US: +35% cc

• Ex-US: +38% cc

Confidence in future growth

• Strong guideline position² (US/EU); 2024 ACC ECDP update strengthens ARNI position as 1L RASi for HFrEF

• Further penetration in HF globally and HTN in China/Japan³

• US: For forecasting purposes, we assume Entresto® LoE in mid-2025

• EU: RDP to Nov 2026⁴

See last page for references (footnotes 1-4). ACC ECDP – American College of Cardiology Expert Consensus Decision Pathway. ARNI – angiotensin receptor neprilysin inhibitor. HFrEF – heart failure with reduced ejection fraction. TRx – total prescriptions. HTN – hypertension. LoE – level of evidence. RASi – renin-angiotensin system inhibitors. RDP – regulatory decision period. Distribution of non-IFRS measures can be found on page 34 of Interim Financial Report.

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Now moving to Slide 6, and we'll walk through the brands one by one as we always do. First, with Entresto®, we had double-digit growth, up 36% in quarter 1. That was, again, geographically broad-based, US and ex-US. In the US, our weekly TRx continue to reach new highs. We had 38% constant currency growth outside of the US. And we continue to see momentum for this brand. We're in a strong guideline position both in the US and in Europe. We have further penetration opportunities in heart failure globally and specifically in hypertension in China, in Japan and in Japan, we have protection into the early 2030s with this medicine.

For forecasting purposes, no change in our Entresto® LoE outlook, continue to guide to a mid-2025 LoE while continuing to aggressively defend our various patents. And then in terms of the EU, we continue to guide to RDP in November 2026 benefiting from our pediatric extension.

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Cosentyx® grew +25% in Q1, fueled by demand in core indications and strong launches

Sales evolution
USD m, % cc

■ US ■ Ex-US

Region	Q1 2023	Q1 2024
US	528	661
Ex-US	548	665
Total	1,076	1,326

Strong growth across geographies

- US: +25% cc
- Ex-US: +24% cc

Highly competitive in core indications (PsO, PsA, AS, nr-axSpa)

- No.1 IL-17 in US dynamic market
- Leading originator biologic in EU and China

New launches accelerating growth

- HS: Dynamic market leadership (>50% NBRx) in US and Germany
- IV: Solid adoption in US ahead of permanent J-code (confirmed for July)

PsO – psoriasis, PsA – psoriatic arthritis, AS – ankylosing spondylitis, HS – Hidradenitis suppurativa, IL – interleukin, IV – intravenous, NBRx – New to brand prescriptions, nr-axSpA – non-radiographic axial spondyloarthritis, IV formulation indication: PsA, AS, nr-axSpA. Constant currencies (cc) is a non-IFRS measure. An explanation of non-IFRS measures can be found on page 34 of the Interim Financial Report.

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Now moving to Slide 7. Cosentyx® grew 25% in the quarter, and I think really got back to the dynamic growth we expect for this medicine. This was fueled both by our core indications, but also some strong launches, and I'll go through that in a bit more detail. US was up 25% in constant currency, ex-US, 24%. We had highly – we're highly competitive in our core indications. And so we saw a return to market share improvement in psoriasis and in the rheumatology indications both in the US and in Europe. And we're now the leading originator biologic in the IL-17 class in EU and China.

Now in terms of our new launches, we saw very strong performance in HS, hidradenitis suppurativa, where we have over 50% now NBRx share versus adalimumab in US and Germany. When we compare our launch on a comparable basis to the adalimumab launch in this indication, we currently see ourselves at nearly 3x the performance of that previous launch. I think really highlighting how strong the uptake for Cosentyx® has been in this new indication.

We also had very strong performance from the contrib/printable-footer J-code, which we expect in Q4. Again, that module's interest was driving pdf templates/printable-footer.html.

the rheumatology indications. So we'll look forward to further acceleration in the back half of the year once we have that J-code in place.

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Kesimpta® delivered 66% growth on the quarter, driven by strong growth in US and increasing penetration ex-US

Sales evolution

USD m, % cc

■ US ■ Ex-US

Region	Q1 2023	Q1 2024
US	295	415
Ex-US	89	222
Total	384	637

+66%

Strong growth trajectory across all regions

- >100k patients treated worldwide, majority naïve or first switch¹
- US (+41% cc): Demand-driven growth, NBRx volume +26% vs. PQ²
- Ex-US (+152% cc): NBRx leadership in 7/10 major markets¹

Compelling product profile

- ALITHIOS 6-year OLE data demonstrates sustained efficacy and consistent safety profile^{3,4}
 - 9 of 10 Kesimpta® patients free of disease activity (NEDA-3) at year 6 in both continuous and switch groups³
 - Treatment-naïve patients derive substantial benefits across multiple markers of disease activity⁴
- 1 minute a month self-administered dosing at home/anywhere⁵

See last page for references (footnotes 1-5). NBRx - new to brand prescription. NEDA - no evidence of disease activity. OLE - open-label extension. Constant currencies (cc) is a non-IFRS measure. An explanation of non-IFRS measures can be found on page 34 of the Interim Financial Report.

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Now moving to Slide 8. Kesimpta® delivered 66% growth on the quarter, and this was again global US and ex-US driven. We have over 100,000 patients treated worldwide on the medicine, and the majority of these patients are either naïve or first switch, which reflects the strategy we have for this brand.

In the US, we saw a very strong demand-driven growth with NBRx volume at plus 26% versus prior quarter. And one of our key priorities now in the US is to increase our B-cell market share over the coming quarters. Outside of the US, we have leadership now in seven out of ten major markets, and we look forward to continuing to drive the convenience and high efficacy story that Kesimpta® presents in these markets.

In the quarter as well, we announced the ALITHIOS 6-year long-term data, which demonstrated sustained efficacy and the consistent safety profile for Kesimpta®. In this study, nine out of ten patients were free on the NEDA-3 score of disease activity. And we also saw treatment-naïve patients derive substantial benefits across multiple markers of disease activity. So even in the face of some competitor launches, we feel very confident about the one minute a month self-administered dosing, high efficacy, strong safety profile of Kesimpta®.

Slide 9

Now over the course of 2024, we're going to focus on share expansion within existing sites and particularly expanding the referral network of medical oncologists who can refer into a Pluvicto®-treating center, we feel like this will be the key now in the post-taxane setting. We also want to build our business outside of the United States with some important launches in Europe as we also build towards launches – planned launches in Japan and China, both countries where we have planned new manufacturing facilities to support the Pluvicto® and Lutathera business.

Our existing indications are also on track. We announced earlier this quarter that the PSMAfore submission-enabling OS readout was achieved. And this will put us in a position to file Pluvicto® early in the second half, so a midyear filing for this medicine. And then PSMAAddition also on track as well as the PSMA delayed castration localized oligometastatic program as well.

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Leqvio[®] adoption continued to expand steadily across the globe

US: Continued growth, outpacing advanced lipid-lowering market¹

Ex-US: Rollout continues

New data at ACC and simultaneous JACC publication support early initiation with Leqvio[®]

Sales evolution

USD m, % cc

■ US ■ Ex-US

Q1 2023

Q1 2024

64

27

37

151

77

74

+139%

See last page for references (footnotes 1-2). ACC – American College of Cardiology. HCP – healthcare professional. JACC – Journal of the American College of Cardiology. LDL-C – low-density lipoprotein cholesterol. Constant currencies (cc) is a non-IFRS measure - explanation can be found on p34 of Interim Financial Report. Novartis obtained global rights to develop, commercialize Leqvio under license/collaboration agreement with Alnylam Pharmaceuticals.

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Now moving to Slide 12. Leqvio[®] also had a really strong quarter. Adoption expanded steadily in the US, but also outside of the United States, as you can see here, on the left-hand chart, very strong performance, both in the US and outside the US. Taking the US first, we had growth outpacing the advanced lipid-lowering market. We have now nearly 3,900 facilities that are ordering Leqvio[®], increased breadth and depth across our key accounts. We continue to see buy and bill as the key driver overall of the business. But we do see also the use of other channels as well.

Outside of the US, we have a consistent rollout. Now we have 29 countries where Leqvio[®] is publicly reimbursed and an additional 39 with private commercial coverage. This puts us in a strong position with our top three European markets contributing 50% of international sales, but really strong growth across the international region. And strong early uptake in China in the self-pay setting with over 200 new patients a day ahead of our planned NRDL listing in the first part of next year.

Lastly, we had new data at ACC and a publication as well, which supported the early initiation of Leqvio[®], demonstrating that starting Leqvio[®] early in patients requiring secondary prevention for a cardiovascular event, a lot of these patients do achieve their LDL-C goals earlier.

Slide 13

Now turning to Fabhalta®. We're at the early stages of the PNH launch, and we didn't expect really to see significant sales at this very early stage, given the complexity of this launch. But we are very pleased with the early launch indicators, we've had a rapid increase in the number of HCPs who are certified under the REMS program, an increase in new writers and patient starts, which are exceeding our internal expectations, we see uptake across naive and switch patients for this medicine.

And we also are really happy to see HCPs willing to work through the medical exception process to get patients on this medicine. So we've also have the positive CHMP opinion for PNH, and we expect that full approval to happen in the coming few months. And we'll consistently work to launch this medicine across the globe as well as drive rapid uptake in the United States.

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INNOVATION

Iptacopan Ph3 APPLAUSE-IgAN study demonstrated 38%¹ proteinuria reduction relative to placebo

Study design

Interim analysis n= 250

End of study n = 518

Day 1

Month 9 proteinuria

Month 24 eGFR

Iptacopan 200mg BID

Placebo

Option to roll-over in OLE

Proteinuria reduction in IgAN patients¹

Group	n	Proteinuria reduction
Iptacopan	118	43.8%
Placebo	106	9.0%

- Clinically meaningful and statistically significant proteinuria reduction vs. placebo
- Complement activation is a key driver of glomerular inflammation in IgAN
- Favorable safety profile consistent with previously reported data
- ~30% of high-risk patients² progress to kidney failure in ~10 years

Next steps

Submitted to FDA and received priority review in Q1; study continues to confirmatory endpoint (eGFR) in 2025

BID – twice daily. eGFR – estimated glomerular filtration rate. IgAN – IgA nephropathy. OLE – open label extension. 1. Adjusted relative % reduction at Month 9 (95% CI): 38.3% (26.0, 48.6); P<0.0001. Perkovic V, et al. Efficacy & Safety of Iptacopan in IgAN: Interim Results, Ph3 APPLAUSE-IgAN. WCN Apr 15, 2024. 2. IgAN patients with persistent proteinuria levels of ≥1 g/day are at higher risk of disease progression. Reich HN, et al. Remission of Proteinuria Improves Prognosis in IgAN. J Am Soc Nephrol. 2007.

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Now turning to Slide 15. We also announced our Phase III APPLAUSE-IgAN study, full results earlier in the quarter, where we demonstrated 38% proteinuria reduction relative to placebo. In this study, we randomized patients to iptacopan versus placebo. The results we read out was the 9-month interim proteinuria analysis. These patients will be – continue to be followed out to month 24 for the full eGFR analysis.

You can see on the right-hand panel, very impressive proteinuria reduction of 43.8% versus placebo at 9%, clinically meaningful and statistically significant. We know that complement activation is a key driver of inflammation in IgAN. And importantly, the overall safety profile was consistent with data we've previously reported. We've submitted this data to FDA. And just one clarification, we did not use a priority review voucher for this medicine. The FDA granted us priority review based on the data set that we provided. So this study continues as well for its eGFR readout in 2025, and we look forward to really getting a full approval very shortly – or getting the initial approval in the coming period.

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Expect to continue our innovation momentum in 2024

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2024 selected key events (expected)

	H1 2024	H2 2024	2025 status update
Regulatory decisions	Fabhalta® PNH	EU, JP	CHMP positive opinion in Q1
	Kisqali® HR+/HER2- adj.BC	US, EU	
Submissions	Atrasentan IgAN	US	
	Fabhalta® (iptacopan) C3G	US, EU	US submission shifted to H2
	Fabhalta® (iptacopan) IgAN	US	US submission in Q1, received priority review
	Pluvicto® mCRPC, pre-taxane	US	Submission-enabling OS readout in April
	Remibrutinib CSU	US, EU, JP	Ph3 REMIX-1 and -2 52-week readout in Q1
	Scemblix® CML 1L	US	JP
Readouts	Lutathera® GEP-NET 1L G2/G3	EU	
	Scemblix® CML 1L	Ph3 (ASC4FIRST)	Ph3 ASC4FIRST readout in Q1
	Zolgensma® SMA IT	Ph3 (STEER)	
	XXB750 Hypertension	Ph2	
Ph3 starts	Pluvicto® oligometastatic PC	Ph3	Ph3 PSMA-DC started in Q1
	Opnurasib 1L NSCLC (combo) ¹	Ph2/3	

Adj.BC – Adjuvant breast cancer. C3G – complement 3 glomerulopathy. CML – chronic myeloid leukemia. CSU – chronic spontaneous urticaria. GEP-NET – gastroenteropancreatic neuroendocrine tumors. IgAN – immunoglobulin A nephropathy. mCRPC – metastatic castration-resistant prostate cancer. NSCLC – non-small cell lung cancer. PNH – paroxysmal nocturnal hemoglobinuria. SMA – spinal muscular atrophy. 1. This is a seamless Ph2/3 trial.

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So all taken together, we're on track across our innovation goals for the year. I did want to highlight that we have shifted our iptacopan C3G US submission to the second half. There is no great correlate for efficacy in C3G, given the ultra-rare nature of this disease. We provided the FDA our 6-month data. While certainly, we believe that 6-month data was very compelling. The FDA wanted to see the additional 6-month follow-up for these patients after all patients had rolled over on to active. The first 6-month period was randomized, second 6-month period, all patients are on active. So we will complete that 6-month follow-up and then file in the second half. And we remain very excited about the opportunity to bring Fabhalta® as well to patients with C3G.

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... and to deliver >20 key submissions in core therapeutic areas by 2028

INNOVATION

Select key assets submission schedule

Core therapeutic areas

CRM

Immunology

Neuroscience

Oncology

2024	2025	2026-2028		
atrasentan IgAN ¹	pelacarsen ² CVRR-Lp(a)	Cosentyx® Tendinopathy	ianalumab Sjögren's syndrome	Pluvicto® Oligometastatic PC
iptacopan IgAN ¹	Pluvicto® mHSPC	Cosentyx® Polymyalgia rheumatica	ianalumab Lupus Nephritis	remibrutinib CINDU
iptacopan C3G	Zolgensma® SMA IT	ianalumab 2L ITP	ianalumab SLE	remibrutinib Multiple sclerosis
remibrutinib CSU	Cosentyx® GCA	ianalumab 1L ITP	iptacopan IC-MPGN	zigakibart IgAN
Pluvicto® mCRPC, pre-taxane	Leqvio® Hyperlipidemia ped	ianalumab wAIIA	Leqvio® CVRR-LDLc	
Scemblix® CML 1L				

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So moving to the next slide. We also are on track for our range of submissions, '24, '25 and '26 to '28. So we'll continue to keep you abreast of how data sets unfold as well as potential readout timelines as we understand those readout timelines better and really excited about the catalyst new pipeline that we have out through the coming years. So moving to Slide 19, I'll hand it over to Harry.

Slide 19 - Harry Kirsch, CFO of Novartis



Yes. Thank you very much, Vas. Good morning, good afternoon, everyone. I'm now going to walk you through some of the financials for the first quarter. And as always, my comments refer to growth rates in constant currencies unless otherwise noted. Also, throughout the presentation, I refer to continuing operations. And as you see from the numbers, it has been a very strong start to the year.

Slide 20

This brings us already to our full year guidance on Slide 21. So the strong momentum in our business across our in-market growth brands and launches, both in the US and international markets give us the confidence to upgrade both top and bottom-line guidance. We have also a favorable update on generic entry assumptions in US, but that's actually a smaller element of the analysis driving our 2024 guidance upgrade. We now expect net sales to grow in the range of high single-digit to low double-digit and core operating income to grow in the range of low double-digit to mid-teens.

Underpinning our guidance are two key assumptions that no Entresto® and no Promacta® generics will launch in 2024 in US. And to complete our '24 full year guidance, please know that we continue to expect core net financial expenses to be in the range of USD 0.6 billion to USD 0.7 billion. Our core tax rate to be around 16.5%.

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Continuing our shareholder-friendly capital allocation strategy

Investing in the business

Returning capital to shareholders

Investments in organic business

Ongoing investment in R&D and CapEx

Value-creating bolt-ons

Proposed acquisition of Morphosys and Arvinas licensing deal in Q1¹

Substantial cash generation

Consistently growing annual dividend²

USD 7.6bn dividend paid in March/April 2024³ not rebased post Sandoz

Share buybacks

Up to USD 15bn share buyback continuing, with up to USD 11.7bn still to be executed

1. Subject to customary closing conditions. 2. In CHF. 3. USD 5.2bn annual net dividend payment in March, which is the gross dividend of USD 7.6bn reduced by the USD 2.4bn Swiss withholding tax that was paid in April 2024, according to its due date.

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Slide 23, please. Just to highlight that we continue our shareholder-friendly capital allocation strategy in quarter 1, of course, investing in the business alongside returning capital to shareholders. Notably, in Q1, we announced two value-creating bolt-ons in our core therapeutic areas, the proposed acquisition of MorphoSys and the licensing deal of Arvinas, both of which align with our strategic focus in oncology. In terms of returning capital to our shareholders, we paid USD 7.6 billion of our growing dividend in quarter 1. And we also continue our up to USD 15 billion share buyback program and we still have USD 11.7 billion remaining to be executed by the end of 2025.

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Expected currency impact for full year 2024

Currency impact vs. PY

%pts, assuming late-April exchange rates prevail in 2024

FX impact on Net sales

-2	-1	-3	-2
FY	Q1	Q2	FY
2023	2024		

FX impact on Core operating income¹

-7	-6	-5	-4
FY	Q1	Q2	FY
2023	2024		

Actual

Simulation

1. Constant currencies (cc), core results are non-IFRS measures. For information, the FY 2023 results have been restated to reflect the impact of the 2022 Financial Report.

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Already to my final slide, 24, we have outlined some of the details regarding the FX impact. And as you see, in

quarter 1, FX had a 1% negative impact on sales and 6 points negative on core operating income, the latter driven by the strong Swiss francs. And if late-April rates prevail, including the most recent strengthening of the US dollar, we expect the full year impact of currency still to be less than it was in 23Q on a point-for-point basis. On the bottom line, a negative 4%. As a reminder, as this is hard to forecast from the outside and moving all the time, we are updating our – the expected FX impact on our website on a monthly basis. And with that, I hand back to Vas.

Slide 25 – Vasant Narasimhan – CEO of Novartis

Great. Thanks, Harry.

Slide 26

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Strong start to the year with double-digit sales growth and core margin expansion, allowing us to raise guidance for FY 2024

Strong momentum across all key growth brands and geographies

Our pipeline continued to advance, with multiple submissions and submission-enabling readouts

Continued confidence in our mid-term guidance of 5% cc sales CAGR 2023-2028, and 40%+ core operating income margin by 2027

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So as you heard, a strong start to the year with double-digit sales growth, strong core margin expansion. And with the strong momentum we see in the business, we're able to raise our guidance for the year. We saw this momentum across all of our key growth brands and across geographies, I think, indicating the high quality of the performance that we're seeing in the company.

Our pipeline continues to advance with new products in development. And we continue to have confidence in our midterm guidance of 5% constant currency sales growth, '23 to '28, and 40% plus core operating income margin by 2027. So with that, I'll hand it back to Sloan, who will outline some of our upcoming investor events.

Slide 27 – Sloan Simpson, Global Head of Investor Relations

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2024 Novartis investor events

ASCO

June 2, 2024
Chicago, US

Focus:
Scemblix ASC4FIRST data and CML 1L opportunity

Renal Pipeline


H2 2024
Virtual

Focus:
Renal portfolio including iptacopan, atrasentan and zigakibart

Meet Novartis Management

November 20-21, 2024
London, UK

Focus:
Dialogue with management

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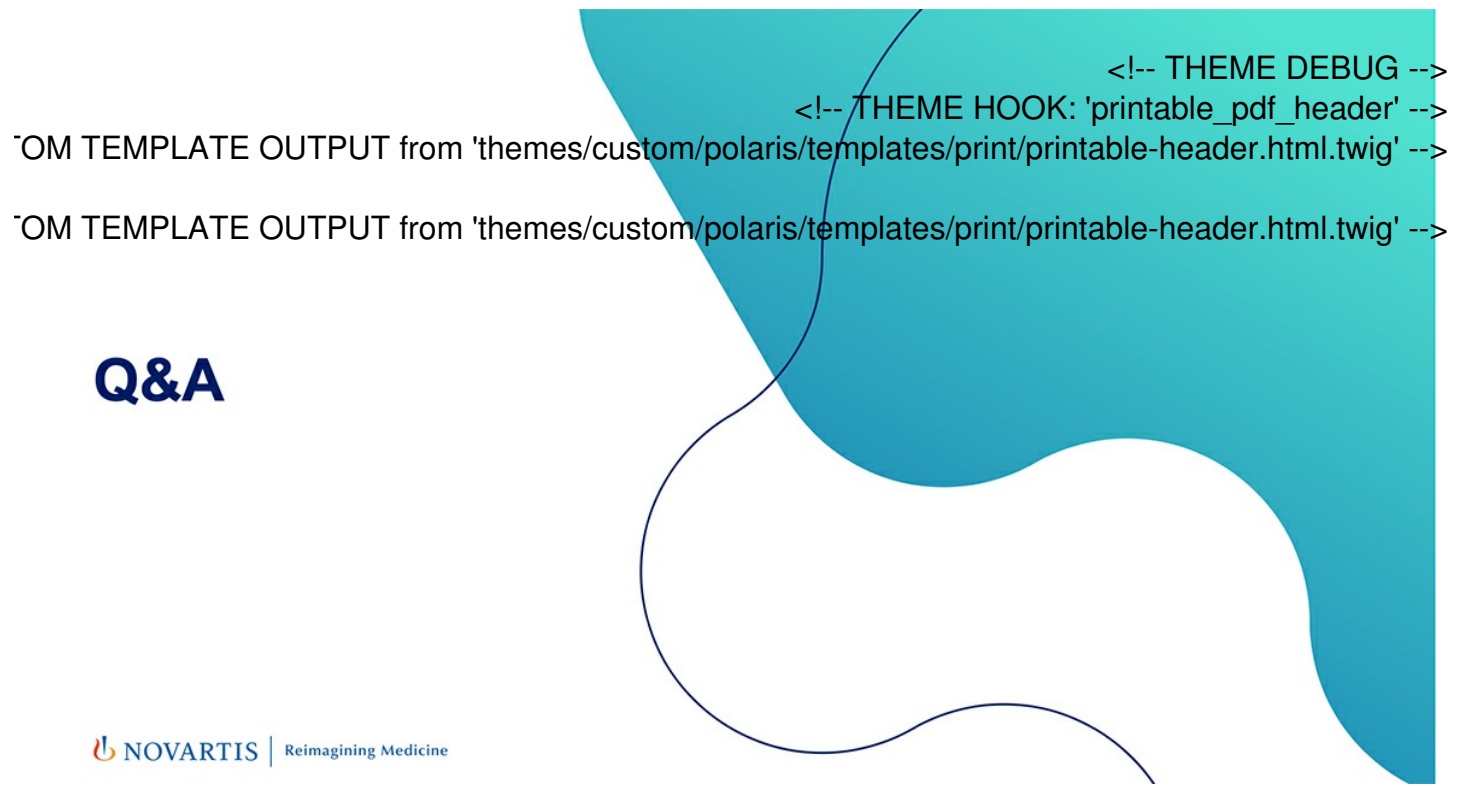
Novartis Q1 Results | April 23, 2024 27

Thank you, Vas. Before we open up for questions, I just wanted to flag a few investor events that we're planning to hold this year. First, we'll have an in-person event at ASCO in Chicago on June 2, highlighting Scemblix® ASC4FIRST data, which Vas mentioned. We'll also have a virtual event on our renal pipeline in the second half of the year. and we'll be having our annual Meet Novartis Management event in London on November 20 to 21. We hope to see many of you at these events. And with that, operator, let's open the line for questions, please.

Q&A session

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Q&A



- Operator

(Operator Instructions) And your first question comes from the line of Matthew Weston, UBS.

- Matthew Weston - UBS Investment Bank, Research Division

Q. It's going to be on Pluvicto®. And so Vas, you set out some of the metrics in terms of improving revenue. I think there's definitely an expectation amongst investors that we might see an inflection as supply comes online and physicians get more comfortable with your ability to supply and add nurses and chairs into their networks. I wanted to understand whether you thought that was a realistic assumption or whether or not investors should get more comfortable with a kind of continuous grind in the growth of Pluvicto® over the coming quarters?

- Vasant Narasimhan – CEO of Novartis

A. Yes. Thanks, Matthew. So first, on Pluvicto®, we have resolved our supply issue, but we are still working through, I think, the remnants of the base of patients that were a bit lower in quarter 4, given that we were still working through things then. And when you think about the growth of Pluvicto® medium-to-long term, first, we have this post-taxane indication, where you can see we're already annualizing at a pretty healthy blockbuster, USD 1 billion-plus sales range.

And we expect that to steadily grow, and we guided to that indication to being a multibillion dollar, so a USD 2 billion-plus indication. So we expect it to steadily grow over the coming quarters in that post-taxane setting. And this will be primarily driven by, as I mentioned, expanding the base of medical oncologists who are able to refer into the existing centers. We don't see the opportunity at this point in terms of expanding the number of centers for this indication.

So that will steadily grow over the course of 2024 to get us steadily marching up towards that multibillion-dollar guidance, USD 2 billion-plus guidance that we've given in the VISION indication. Then we expect the PSMAfore pre-taxane indication to be the next catalyst, and we do expect an inflection on that launch which will drive the total sales of Pluvicto® to be in the USD 3 billion-plus range. And we expect that to be the start of a new era of growth for Pluvicto®.

bring on board Germany, France, other countries in Europe. And then in the coming years, we do expect a substantial inflection from China and Japan. We're building dedicated manufacturing facilities for those countries in order to drive further growth, both in the pre-taxane and the post-taxane indication. Next catalyst will be the pre-taxane approval, which we hope to have in the first half of next year. Then the common bile duct indication from the eras. So I think a steady growth in the VISION indication within catalysts coming from ex-US expansion and the indication expansions for the brand.

- Operator

Your next question comes from the line of Steve Scala from TD Cowen.

- Stephen Michael Scala - TD Cowen, Research Division

Q. Vas, you noted in the prepared remarks that the Kisqali® review was on track, but how confident is Novartis that FDA will meet the priority review regulatory deadline for Kisqali® with a broad label? There seems to be a number of things that could give FDA pause, including the nitrosamine issue as well as liver tox. So what is your level of confidence?

- Vasant Narasimhan – CEO of Novartis

A. Yes, Steve, we're very confident on the broad label. I think on the timeline, we currently guide to the current timeline that we have as we implement these manufacturing shifts. We of course, are discussing these manufacturing adjustments and they're minor adjustments, but they do require discussions with FDA. And so once we have a better clarity on – if at all, if there was any shift in timeline, we would, of course, let the markets know. But we think this will be still a second-half launch for this medicine, and we feel very good about that guidance. And so while we talk here about minor shifts, we're not talking about anything significant. And again, expect the broad label.

We don't have concerns about liver. This is something that's well known with Kisqali®, LFTs are currently monitored in the metastatic breast cancer setting. No change in monitoring requirements is what we expect. So overall, we feel good with the ability to launch this medicine in the second half of the year.

- Operator

Your next question comes from the line of Graham Parry, Bank of America.

- Graham Glyn Charles Parry - BofA Securities, Research Division

Q. Another one on Kisqali®, just – could you just explain just what the process amendment needed for Kisqali® is in early breast cancer? So is that something in the actual reaction? Is it purification? And do you know at the moment whether you do or don't need an inspection by FDA? And if there is one, do you think that would still be completed within the second quarter time frame and therefore, not delay the NATALEE PDUFA timeline.

- Vasant Narasimhan – CEO of Novartis

A. Graham, So first on the manufacturing adjustments that we talked about here. Just as a reminder, Kisqali® already meets the requirements in metastatic breast cancer. So these are just additional requirements given that early breast cancer is an asymptomatic population. The adjustments we talked about here are primarily how we source material from third parties. We want to go to higher quality sourcing of third-party material which is something we believe we can implement in a very straightforward way. And then also just some

additional adjustments within our supply chain for the management of Kisqali® prior to actually leaving our supply chain to go to physicians.

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- Operator

Your next question comes from the line of Emily Field from Barclays.

- Emily Field - Barclays Bank PLC, Research Division

Q. I just want to ask a question on Cosentyx®. I know you mentioned you're expecting the J-code, but are you currently generating much sales from the IV formulation just in that context, if you could frame the current pricing environment in the US specifically?

- Vasant Narasimhan – CEO of Novartis

A. Yes. Thanks, Emily. So Cosentyx® IV, I'd say better-than-expected uptake than what we had thought prior to the J-code. But when you look at Cosentyx® current outperformance in the quarter, it was driven primarily by the strong hidradenitis suppurativa launch as well as that leading to stronger performance as well in psoriasis globally. So the IV launch is still, I think, in the midst of kicking up.

What I would say is we are having a – we have reached already the vast majority of accounts that we expected to order Cosentyx® IV. They're already at least in the process of ordering the medicine ahead of the J-code, trying to use an exceptional code to use the medicine. So in terms of account reach, we're already in a very good position. And we think we'll be able to then drive a strong depth once we actually get the J-code in place. So we feel very good. So this could be another, I think, good driver for Cosentyx® growth in the second half post that J-code being rolled out.

- Operator

Your next question comes from the line of Simon Baker, Redburn Atlantic.

- Simon P. Baker - Redburn (Europe) Limited, Research Division

Q. It's a broad question on the commercial performance. Vas, you've highlighted a few specific reasons for strength in the quarter like the Cosentyx® HS launch but to what extent is the broad-based performance we've seen in this quarter, a result of the changes to the commercial organization that have been underway over the last couple of years? I wonder to what extent that is responsible if you could give any color on where it's impacting? And how much is there left to come from that initiative?

- Vasant Narasimhan – CEO of Novartis

A. Yes. Thanks, Simon. We do believe that probably the biggest – big picture driver for our strong performance over the recent quarters has been the reorganization and focus of the – focusing of the company. And as a reminder for investors, a few things we did, we elevated the US and we went to a geographic model, US, international; we focused down the portfolio to four key therapeutic areas; we focus the commercial area on nine key drugs; we shifted our investments in most places, over 75% of the M&S investments go to the growth drivers; a heavy focus on US, China, Japan and Germany. And taken together, that I think is compounding to show the broad-based performance you see across the US and international and particularly in some markets like China, very, very strong performance.

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So that is, I think, the biggest sustainable driver. In terms of specifics in the quarter, clearly, Cosentyx® performed extremely well. Putting aside consensus, if you look at the growth rates of Kisqin® and Kisqin®,> Leqvio®, Scemblix® these were all very, very strong, even Pluvicto®. If we put aside the quarter-on-quarter growth. These were all very strong growth rates. And I think that also, I think, gives us confidence to raise the guidance for the full year.

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Your next question comes from the line of Emmanuel Papadakis from Deutsche Bank.

- Emmanuel Douglas Papadakis - Deutsche Bank AG, Research Division

Q. Since you flagged it will be forthcoming at ASCO, perhaps just a question on Scemblix® ASC4FIRST data details. The primary end point was MMR so we're going to be very interested to see how that fares, obviously, to physician standard or physician's choice, standard care control arm versus the potential comparators in particular, Gleevec® there, can you talk a little bit about what we could expect to see in terms of some of the standard-of-care competitors on that primary endpoint? And indeed, any secondaries you're willing to provide thoughts would be helpful as well.

- Vasant Narasimhan – CEO of Novartis

A. Yes. Let me outline how the Scemblix® study was designed and then hopefully give you some perspective. So this was a first-line study, and this is, of course, our third medicine in the world of chronic myelogenous leukemia, so a long history in the company.

The primary endpoint was Scemblix® versus investigator choice TKI with a goal that over 50 – roughly 50% of patients would be on imatinib or Gleevec®. And the primary endpoint was Scemblix® versus the overall pool of patients' intention to treat regardless of TKI. So that's first primary endpoint. And the co-primary endpoint was Scemblix® versus Gleevec®. And we hit both of those primary endpoints with clinically meaningful, highly statistically significant improvements in MMR.

Then we had a descriptive secondary endpoint of Scemblix® versus the two second-gen TKIs. And again, there, we will disclose the full data at ASCO, but we feel very good about the profile of the medicine. And then on safety, which I think is one of the key elements of Scemblix® story already in the third-line setting, we saw outstanding safety profile. So I think that's the other thing to look out for at the ASCO presentation is the overall safety profile of Scemblix® because clearly, to move into that frontline setting, physicians will want to see both strong efficacy and a clean safety profile.

Now it's important to note that once we get to the point of filing the medicine shortly and then ultimately launch the medicine, in the US, we believe there's a portion of the market where we can drive very rapid uptake. These are patients who are currently on second-gen TKIs or in physician practices that are very open to switching.

We do know that there is an element of the CML market that's contracted and that tends to use generic imatinib, that will take us longer to – overall to move through. But I think one of the exciting things about Scemblix® is that this has a long LoE and based on targeting a rare disease, it's not part of IRA negotiations.

So we have here a medicine that can drive Novartis growth through this decade and well into next decade, both US and around the globe. And we, of course, are one of the global leaders in CML. So I think that positions us well overall.

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Your next question comes from the line of Richard Vosser from JPMorgan.

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- Richard Vosser - JPMorgan Chase & Co, Research Division

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Q. Can I return to Cosentyx®? And you mentioned the launch in HS being sort of 3x Humira. How do you see the sizing of the indication of HS now? Is that a USD 2 billion to USD 3 billion indication for Cosentyx®? And thus, do you see continued potential double-digit growth over the next few years for the product?

And I suppose one just clarification just to – any quantification on the HS – size of the HS contribution at this stage? And I don't think there was any pricing or stocking in the first quarter, but just to clarify that as well.

- Vasant Narasimhan – CEO of Novartis

A. Yes. Thanks, Richard. So just as context, we estimate as best we can from public information that adalimumab had over USD 1 billion in sales in HS historically. We do think that the market is significantly underserved. There's a large number of patients who are not on biologics in this indication. So it could be a substantial market.

I don't think we've given yet guidance on specifically the overall size of the market. But certainly, there's a potential of a multibillion-dollar market here. So we think Cosentyx® has the opportunity to drive very significant growth for the brand as we try to reach USD 7 billion, probably not in a position yet to give specific indication-based guidance on Cosentyx®, but we think with the combination of HS, of IV, giant cell arteritis Phase II, which is ongoing, the Polymyalgia Rheumatica indication that we also have as well as the strong performance we have in China that just gives us even more conviction that we can get to that USD 7 billion peak sales by the end of the decade.

- Operator

Your next question comes from the line of Tim Anderson, Wolfe Research.

- Timothy Minton Anderson - Wolfe Research, LLC

Q. I have a couple of questions on Entresto® and just timing of generic entry. So in the US, can you map out for us what we should be tracking from here in terms of events and news flow that will help inform whether mid-'25 is a good assumption. And as we've conceived well that sometime in '24, you'll have a different point of view.

And then ex-US and the timing of generic entry, you guide for later '26, is there a similar level of uncertainty on that and then if you could wrap-in China as part of that discussion on generic timing as well.

- Vasant Narasimhan – CEO of Novartis

A. Yes. Thanks, Tim. So on Entresto® right now, we do have an appeal ongoing to the Circuit Court on the combination patent, which we believe will be heard and ruled on in the second half of this year. It's important to note that there have been no Entresto® generics approved as of yet, and we have two citizen's petitions pending at the FDA on the basis for approval and also the labeling for any potential product with respect to Entresto®.

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So based on that fact that we don't expect any generics to launch this year that we can never exclude, of course, somebody trying to do something at risk. And then separate from that, we have a number of other patents that are currently being litigated towards the end of this year and then towards the – all through the coming period, which is what overall makes us have the best estimate in the US of mid-2025. And of course, as we get better resolution on that, we can, of course, provide further color.

I would also say that Entresto® is on the IRA negotiation list so that we would expect in Jan 2026 to our best understanding, at least in the Medicare population that IRA pricing would hold, and we would get a better lead on how that looks in September. Outside of the United States, we already include our pediatric exclusivity. So we think our current guide of end of 2026 is reasonable. Of course, we're always looking for ways to

adequately defend all of our patents, but we think that's a very reasonable assumption at this point in time.

In China, at the moment, we currently have, I think, a number of different approaches, but the key there will be the number of generics and when they get approved. And so I think we could reasonably expect potential entry of Chinese generics sometime in the course of 2025. But the question in China was when we will enter the VBP list. And that, of course, is something we're monitoring. And once we have a better understanding of the number of generics and their status legally when we enter the VBP list, we'll be able to provide further clarity.

And lastly, in Japan, we currently outlook 2031, I believe – 2031 or 2032. Our team will get back to you exactly. But certainly into the 2030s for Japan at the current point in time. So hopefully, that's helpful, Tim. Thank you for the question.

- Operator

Your next question comes from the line of Richard Parkes, BNP Paribas.

- Richard J. Parkes - BNP Paribas Exane, Research Division

Q. Just wondered if you could help us with cost phasing. I think guidance is implying a lower margin improvement than the very strong margin improvement you saw in Q1. And I know that was slightly mismodeled last year going into Q4, extrapolating the margin. So can you just help us understand the phasing in terms of costs over this year? That would be very helpful.

- Vasant Narasimhan – CEO of Novartis

A. Thanks, Richard. I'll hand that to Harry. Harry?

- Harry Kirsch – CFO of Novartis

A. Thank you, Richard. So overall, as you have seen, our quarter 1 costs were growing in constant currency, roughly 2%, which was driven by R&D right up – roughly 6%, whilst SG&A was basically flat. That's a consequence also of the full implementation of transformation for growth, restructuring programs, leaning out, going to one organization locally between pharma, onco and leaning out above country and customer-facing functions, our organizational structures and leaning our processes. So we see some continued benefits from that.

Of course, we will continue to leverage new technologies, leaner processes to keep driving the multiple launches. But all within our four therapeutic areas where we have significant commercial infrastructures and medical infrastructures. So I would expect that SG&A continues to be quite flattish. Maybe here or there a bit more investment, but certainly significantly below sales growth.

And then the level of especially development spend depends also a bit on the M&A, in-licensing agenda. So clearly, we have some placeholder for that in the second half of the year as well. And then we will update you after Q2, of course, how things are going, which we have a better picture of. But overall, very good focus on cost consciousness. As was mentioned, excellent resource allocation to our top line brands and pre-launches. And with that, as always, outlook. The key contribution to our margin growth is expected to come from SG&A as we expect very dynamic sales growth this year and on a 5-year basis and very limited SG&A growth.

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Your next question comes from the line of Mark Purcell from Morgan Stanley

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- Mark Douglas Purcell - Morgan Stanley, Research Division

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Q. It's on Scemblix®. I wonder, Vas, if you could help us understand the level of uptake you anticipate in the first-line setting. The slide shows 40% NBRx share in the third-line setting, and you talked about the sort of potential ease of identifying specific patients who might most likely benefit from Scemblix® versus the current standard TKIs.

And I also wondered on Scemblix®. Have you seen any early impacts of the Part D redesign when it comes to treatment initiations and volumes? Any sort of comment there for Scemblix® and across your business would be great.

- Vasant Narasimhan – CEO of Novartis

A. Yes. Thanks, Mark. I think on Scemblix®, we would expect, I would say, a modest early uptake because we would have to work through – CML is one of the few cancer areas that's currently contracted. And so we would need to work through the access in the first couple of quarters from launch. But then after that, we believe that given the overall data set that we'll share at ASCO, that it should be able to drive very strong uptake.

And of course, you all know well that the second-gen TKIs were on the order of USD 2 billion medicines. Gleevec® was a USD 4 billion-plus global medicine. And so certainly, our goal is to make this over time, the leading CML treatment in the world. we wouldn't face any competition, at least branded competition and given that we will have demonstrated MMR superiority over the pooled group of Gleevec® and the second-gen TKIs. It should put us in a very good position over time to make this into a significant medicine.

I think on Part D redesign, it's really early days for us to have a strong sense of the impact. And so we're monitoring this very closely, also reading all of your reports on how you're monitoring it to really understand what is the impact of out-of-pocket caps and some of the other shifts that are happening in the system on patients taking up their medicines.

I think certainly, as we move down from a USD 3,500 cap to a USD 2,000 cap, I would expect, in general, to see more patients' ability to fulfill their medicines to improve as the cost becomes lower at the pharmacy counter. But we need to see that, I think, in the data before we can really provide you more color.

- Operator

Your next question comes from the line of Peter Welford from Jefferies.

- Peter James Welford - Jefferies LLC, Research Division

Q. It's on the planned proposed MorphoSys transaction. I wonder if you can just outline when you did that, how much of the acquisition price that you're considering was based on getting broad, both geographical and same to the market approval for pelabresib.

And versus, on the other hand, how much of the transaction is described to what you're thinking with regards to the EZH2 and also the imatinib royalties that you would potentially owe and how we should think about, I guess, that deal, the potential – fitting that into the – for Novartis cost structure, business as it is today.

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- Vasant Narasimhan – CEO of Novartis

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A. Yes. Thanks, Peter. Probably, I can't say more than what we've already said, given that we have an ongoing share tender offer out in the market. So what we previously outlined is we believe there is an opportunity globally for pelabresib in both Europe and in the United States, and that's an exciting opportunity given our JAK/STAT business and the opportunity that we have to leverage our long history in myelofibrosis, and position in myelofibrosis outside the United States and our strong hematology footprint inside the United States.

So we would see pelabresib as fitting nicely within that global infrastructure that we have. And yes, we would also benefit from the historical royalties, particularly on imatinib, where we see the opportunity of a significant medicine, both in immunology and in cancer. And so I think that's a pretty exciting opportunity for us to get those royalties back and then hopefully drive very significant medicine with – a significant medicine in a royalty-free way.

And then lastly, the company does have an EZH1/2 inhibitor in prostate cancer that we think could also be very interesting for us going forward. So those are the three components of why we saw value in the deal.

- Operator

Your next question comes from the line of Andrew Baum from Citi.

- Andrew Simon Baum - Citigroup Inc., Research Division

Q. Apologies. Just going back to the ASC4FIRST trial with Scemblix®. Could you just expand your previous comments, Vas, on the dynamics of the CML market, particularly the current market shares in first line, generically versus others, the Medicare versus non-Medicare segmentation, just to help us think about the barriers to entry in a different segment in terms of authorization, step edits.

- Vasant Narasimhan – CEO of Novartis

A. Yes. So Andrew, a couple of things. I think, one, we see this is a market that on the order of 40% – 35% to 40% imatinib so Gleevec® generics and 60% TKIs. And then in terms of commercial and Medicare, we can come back to you with the exact data. But my recollection is it's largely evenly split between Medicare and private commercial plans.

So the way we look at the overall market opportunity in that 60% or so of patients who are on second-gen TKIs, this is an opportunity as this class goes generic to certainly – and for commercial plans as well, given that we won't have to compete against a rebate from those players, we would certainly have the opportunity to educate physicians on the great profile that we have here particularly around the safety profile, also the efficacy profile and then hopefully drive switches.

And we see that's the early opportunity for the medicine in that second-gen TKI, particularly second-gen TKI commercial and then eventually the Medicare. We find that patients who are currently on imatinib tend to be in community oncology and tend to be with physicians who have a long history of using imatinib and therefore, might be more resistant to change. And that will take us longer to eventually, I think – we think, move though. We do think we have good strategies to get there. That segment of the market will be a longer lift for us to eventually move through. So that's in the US setting, I think ex-US will really vary by geography. Certainly, in Europe, it will be critical for us to demonstrate differentiation with imatinib from a payer standpoint to justify what we think is a fair price for the medicine.

We would expect in Japan, in China, the opportunity for strong uptake. These are markets where we do think we can get reimbursed. And certainly in Japan, there's a very well-educated CML physician community. So that's, I think, a relatively large opportunity as well.

So that's kind of the high-level dynamics. But I think at the ASCO presentation in June, we can provide more insights into the overall market structure and how we're seeing the opportunity to launch the medicine.

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Your next question comes from the line of Seamus Fernandez from Guggenheim Securities.

- Seamus Christopher Fernandez - Guggenheim Securities, LLC, Research Division

Q. So really, I just wanted to focus in on IgAN and some of the activity that we're seeing from a competitive perspective there and acquisitions in the space. So I just wanted to get your thoughts on the acquisitions that you've made in IgAN and the opportunity that you see in that space, whether it be for iptacopan or for the acquisitions that you've made? I know you specified a lot of opportunity there. But interested to sort of see if you view this as a validation of the IgAN market opportunity and how you're thinking about the competitive landscape going forward?

- Vasant Narasimhan – CEO of Novartis

A. Yes. Thanks, Seamus. So in general, I mean, IgAN is, we believe, a significant market opportunity. These patients don't have – historically have not had great medicines. They do progress at a relatively high rate in the 10-year period towards needing transplantation or going on to dialysis. And we're talking about a segment here that's over 130,000 patients in the US alone. So we think it is a sizable opportunity.

When we think about the treatment paradigm, you – of course, you start out – you want to – historically, this has been a steroid-driven treatment paradigm, but we think this will shift to wanting to somehow manage the hemodynamic component of these patients where we have atrasentan.

You want to manage then the inflammatory component for these patients along two dimensions, complement inhibition and APRIL inhibition as well. Now we're in a position where we will have atrasentan for hemodynamic inhibition. We'll have iptacopan for complement inhibition, and we'll have ZigaKibart also acquired in our Chinook acquisition for the anti-APRIL component. We acknowledge there will be competitors, particularly on the anti-APRIL side of things where we're going to have a few other competitors enter.

We believe we'll be the only company positioned with really the full range of hemodynamic, complement, ANTI-April. I should note as well, of course, upstream the SGLT2 inhibitors, which are also going generic will also be part of that early-treatment paradigm. But post SGLT2 inhibitors and perhaps generic hypertensives, you're going to want to move down this paradigm of really more potent hemodynamic control and then also trying to get to the inflammatory component.

And we think having three medicines will allow us to be well positioned with patients, physicians, contracting the various elements of the US supply chain and also globally. So that's how we're approaching it. I do think the recent acquisitions do point to that anti-APRIL and this whole area is exciting, right? And we have an asset there, others now are also coming but certainly something we're looking at very carefully to also see can you expand APRIL inhibition with or without BAFF inhibition for other indications as well.

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Your next question comes from the line of Eric Le Berrigaud from Stifel.

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- Eric Le Berrigaud - Stifel, Nicolaus & Company Incorporated, Research Division

Q. We saw the split in sales by geography on Leqvio® being significantly different from the past and now ex- US being more significant than US. Could you maybe elaborate a little bit on the kind of agreements you

reached in ex-US territories, maybe the main three markets in Europe and China, how the drug is delivered? How are you billing for the drug in those geographies?

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A. Yes. Thanks, Eric. We're pleased to see Leqvio® now getting to a steady march upward in terms of its overall sales growth. Outside of the United States, there have been a few key dynamics. So first is China self-pay, where I mentioned over 250 patients a day, steady growth as well in terms of the number of patients that were being able to get on treatment in China. And that's ahead of where we hope to get listed – full listing on the NRDL in the first part of next year. And given the strength of our cardiovascular operations in China with Entresto®, we believe we can drive pretty significant uptake of Leqvio® over time in China.

We also have reimbursement in Japan, and we're in the very early days of launching in Japan. So Japan was not a significant contributor in Q1, but we expect consistently now in the coming quarters, Japan to be a more significant contribution.

In Europe, we've had very steady uptake in the commercial market in Germany as well as improving performance in Italy and the UK. And so I mean, the UK has been a disappointment relative to where we hoped it would be, but nonetheless, it's steadily moving up as well. And then interestingly, while it's a smaller contributor, given the number of countries around the globe, we have reimbursement, we do have public health agreements in places like the Gulf Coast countries as well as other markets in our international business that's also contributing.

So step by step, all of this comes together to drive the performance that you saw in quarter 1. And we'll see. We hope we can continue that now in the coming quarters and steadily get Leqvio® up to that multibillion-dollar outlook that we've given.

- Operator

Your next question comes from the line of Steve Scala from TD Cowen.

Stephen Michael Scala - TD Cowen, Research Division

Q. On Entresto®, were there any onetime factors driving Q1 sales such as rebates and/or inventory? If not, then what in your opinion led to it not tracking prescriptions in the quarter?

- Vasant Narasimhan – CEO of Novartis

A. Yes, Steve, we're not aware of any one-timers on Entresto®. We saw strong TRx growth. We saw outstanding growth in China. And I think that was a big driver of the performance you saw in the quarter, also steady uptake in Japan. But no one-timers that we're aware of. Looking at Harry, yes. So no one-timers that we see. This was just underlying performance, and I think driven both in the US but also China and Japan.

- Operator

Your next question comes from the line of Graham Parry, Bank of America.

- Graham Glyn Charles Parry - BofA Securities, Research Division

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Q. Just wondering in terms of the NK1A2L changes that we were talking about, timing, just what

assumed in your guidance for adjuvant breast cancer for Kisqali® for this year? So there's any significant contribution in there, or is that de minimis at this point?

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And then just I'll flip in the second one, just at the ASCO event, on Scemblix®. So I was wondering if you're going to be in a position to give some sort of updated peak sales guidance for that asset? There's obviously a lot of questions on the call about market appetite that's – what everyone's fishing for.

- Vasant Narasimhan – CEO of Novartis

A. Yes. Thanks, Graham. On NATALEE, not a material contribution or really any contribution in this year. So I don't think that's something that needs to be factored in, in terms of our guidance. On Scemblix®, we'll take it under advisement. I can't commit one way or another, but we'll certainly take the feedback on trying to guide. It's always tough, of course, before we've even got an approval or launched a medicine to really know the outlook. But I think we've got reasonable benchmarks in the CML market with Gleevec® and the second-gen TKIs. And as I outlined, we really believe, but we'll see as we present the data that this can be really the best-in-class medicine to treat CML that's been launched in this industry. So we hope we can live up to that profile.

- Operator

And your final question today comes from the line of Emily Field, Barclays.

- Emily Field - Barclays Bank PLC, Research Division

Q. Question on ionalumab, given that this morning, we did see Phase III success in ITP from a competitor BTK inhibitor. So I was just wondering given that you also have a BTK inhibitor of your own, why you're pursuing ITP with the BAFF inhibition and you think that, that's the right mechanism of action? And while you're also prioritizing second line or first line, I believe that's what it says, the lead indication in the slides.

- Vasant Narasimhan – CEO of Novartis

A. Yes. So first, on BTK inhibition, we really tried to focus our BTK inhibitor outside of the oncology indications. I mean we look at the indication range we're pursuing, it's immunology, the full range, HS, food allergy, CSU. We have also ideas to pursue remibrutinib in other immunology indications and multiple sclerosis.

So we've tried to steer clear of the oncology setting overall and really focus ionalumab in both oncology but also in more hard-to-treat immunology indications. Based on our best guidance from FDA and the agreements on the Phase III study, we think this was a stepwise approach in ITP, especially for a subcu medicine like ionalumab. And then, yes, we'll see if we can move into the frontline setting.

So I think that's probably the best guidance I can give. I'm trying to recall if we looked at remibrutinib in ITP, but we'd have to get back to you, Emily, I just can't recall if we looked at it in our Phase IIa programs. So we can come back to you if we have studied our BTK inhibitor in those indications.

So thanks very much. I think that was the last question. So I really appreciate everybody's time today. We look forward to keeping you updated, and we will see you all at our event at ASCO. So thank you and have a great quarter season and wish you a great spring.

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