

# R&D Event

March 27, 2024

### **Forward Looking Statements**

This presentation contains "forward-looking statements". These statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements may include, without limitation, statements about significant financial flexibility and multiple levers to drive future growth; well-positioned to unlock shareholder value; simplified and stable base business, reduced footprint and increase portfolio concentration in higher value chain opportunities; improving leverage profile with line of sight to gross leverage target; increasing capital return, guarterly dividend and execute share buyback; investing in growth, pursue business development opportunities to further accelerate revenue growth; balanced capital allocation framework; expect at least \$2.3 billion in free cash flow annually with 50% for reinvestment into the business and 50% returned to shareholders via quarterly dividends and share buyback; organic revenue growth to fuel and grow the base business and leverage regional advantage; pursue BD for new growth to develop core therapeutic areas and opportunistically expand scope: Idorsia collaboration is an important step in our return to growth strategy: expands our portfolio of innovative assets by immediately adding tow phase 3 assets, seatogrel and cenerimod, both with blockbuster revenue potential and long-dated patent protection: includes future optionality to expand collaboration with additional innovative assets: combines our financial strength and worldwide operational infrastructure with Idorsia's proven highly productive drug development team and innovation engine: deal structure reinforces our disciplined approach to capital allocation: our durable, high-margin organic pipeline; strong R&D and pipeline foundation with consistent track record: deep in-house development capabilities; diverse portfolio and pipeline; proven science track record; robust science, preclinical and device engineering; strong clinical development and medical affairs across multiple therapeutic areas; proven regulatory, legal and IP skills; broad and scalable manufacturing capabilities; number of pipeline products; complex injectables pipeline, 9 FTM potential opportunities, key durable contributor of potential new product launches over next 5 years; select novel and complex products – another growth catalyst; anticipated launch year; expect to deliver \$450-\$550 million in annual new product launches in 2024: eve care portfolio and pipeline. \$1 billion + peak net sales expected: information about AML selatogrel and clinical trials presented on slides 20-37: information about SLE. cenerimod and clinical trials presented on slides 38-61: Idorsia collaboration expands our portfolio of innovative assets and potentially accelerates long-term growth; favorable deal structure; attractive risk-reward; asymmetric risk and return profile to drive strong value creation for shareholders; manageable near-term P&L impact and minimal leverage impact; foundational assets to drive long-term growth; highly novel and differentiated target product profiles with large addressable markets leading to blockbuster potential; exclusivity expected into 2040s provides runway for additional LCM opportunities; delivers on Viatris' return to growth strategy, evolving portfolio mix to more durable, higher-margin assets, opportunity to accelerate long-term revenue growth. R&D collaboration establishes foundation and adds scientific expertise for innovation engine; selatogrel; highly innovative treatment with blockbuster revenue potential; significant market of patients with life-threatening events; potential for AMI survivors to become lifelong selatogrel patients; game-changing profile fulfills significant unmet need; opportunity for first and only patient administered AMI treatment; high value commercial dynamics; multiple expansion opportunities, including high-risk pre-AMI and transient ischemic attack; total addressable market; cenerimod: highly innovative treatment with blockbuster potential; large established addressable patient population; high unmet need for new safe and tolerable options to add onto existing therapies; potential for highly differentiated benefit/risk profile compare to current treatments; high value commercial dynamics; cenerimod's MoA is optimally suited to target multiple autoimmune and inflammatory diseases; additional revenue opportunities in diseases linked to lupus, rheumatic diseases and indications with approved S1P therapies; the goals or outlooks with respect to the Company's strategic initiatives, including but not limited to the Company's two-phased strategic vision and potential and announced divestitures, acquisitions or other transactions; the benefits and synergies of such divestitures, acquisitions, or other transactions, or restructuring programs; future opportunities for the Company and its products; and any other statements regarding the Company's future operations, financial or operating results, capital allocation, dividend policy and payments, stock repurchases, debt ratio and covenants, anticipated business levels, future earnings, planned activities, anticipated growth, market opportunities, strategies, competitions, commitments, confidence in future results, efforts to create, enhance or otherwise unlock the value of our unique global platform, and other expectations and targets for future periods. 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Factors that could cause or contribute to such differences include, but are not limited to: the possibility that the Company may not realize the intended benefits of, or achieve the intended goals or outlooks with respect to, its strategic initiatives (including divestitures, acquisitions, or other potential transactions) or move up the value chain by focusing on more complex and innovative products to build a more durable higher margin portfolio: the possibility that the Company may be unable to achieve intended or expected benefits, goals, outlooks, synergies, growth opportunities and operating efficiencies in connection with divestitures, acquisitions, other transactions, or restructuring programs, within the expected timeframes or at all: with respect to previously announced divestitures that have not been consummated, including the divestiture of substantially all of our OTC Business, such divestitures not being completed on the expected timelines or at all and the risk that the conditions set forth in the definitive agreements with respect to such divestitures will not be satisfied or waived: with respect to previously announced divestitures, failure to realize the total transaction values for the divestitures and/or the expected proceeds for any or all such divestitures, including as a result of any purchase price adjustment or a failure to achieve any conditions to the payment of any contingent consideration; goodwill or impairment charges or other losses related to the divestiture or sale of businesses or assets (including but not limited to announced divestitures that have not yet been consummated); the Company's failure to achieve expected or targeted future financial and operating performance and results; the potential impact of public health outbreaks, epidemics and pandemics; actions and decisions of healthcare and pharmaceutical regulators; changes in relevant laws, regulations and policies and/or the application or implementation thereof, including but not limited to tax, healthcare and pharmaceutical laws, regulations and policies globally (including the impact of recent and potential tax reform in the U.S. and pharmaceutical product pricing policies in China); the ability to attract, motivate and retain key personnel; the Company's liquidity, capital resources and ability to obtain financing; any regulatory, legal or other impediments to the Company's ability to bring new products to market, including but not limited to "at-risk launches": success of clinical trials and the Company's or its partners' ability to execute on new product opportunities and develop, manufacture and commercialize products; any changes in or difficulties with the Company's manufacturing facilities, including with respect to inspections, remediation and restructuring activities, supply chain or inventory or the ability to meet anticipated demand; the scope, timing and outcome of any ongoing legal proceedings, including government inquiries or investigations, and the impact of any such proceedings on the Company; any significant breach of data security or data privacy or disruptions to our IT systems; risks associated with having significant operations globally; the ability to protect intellectual property and preserve intellectual property rights; changes in third-party relationships; the effect of any changes in the Company's or its partners' customer and supplier relationships and customer purchasing patterns, including customer loss and business disruption being greater than expected following an acquisition or divestiture; the impacts of competition, including decreases in sales or revenues as a result of the loss of market exclusivity for certain products; changes in the economic and financial conditions of the Company or its partners; uncertainties regarding future demand, pricing and reimbursement for the Company's products; uncertainties and matters beyond the control of management, including but not limited to general political and economic conditions, inflation rates and global exchange rates; and inherent uncertainties involved in the estimates and judgments used in the preparation of financial statements, and the providing of estimates of financial measures, in accordance with U.S. GAAP and related standards or on an adjusted basis.

For more detailed information on the risks and uncertainties associated with Viatris, see the risks described in Part I, Item 1A of the Company's Annual Report on Form 10-K for the year ended December 31, 2023, and our other filings with the SEC. You can access Viatris' filings with the SEC through the SEC website at www.sec.gov or through our website and Viatris strongly encourages you to do so. Viatris routinely posts information that may be important to investors on our website at investor.viatris.com, and we use this website address as a means of disclosing material information to the public in a broad, non-exclusionary manner for purposes of the SEC's Regulation Fair Disclosure (Reg FD). The contents of our website are not incorporated into this presentation or other filings with the SEC. Viatris undertakes no obligation to update any statements herein for revisions or changes after the date of this presentation other than as required by law.



# Non-GAAP Measures & Key References

#### **Non-GAAP Financial Measures**

This presentation includes the presentation and discussion of certain financial information that differs from what is reported under accounting principles generally accepted in the United States ("U.S. GAAP"). These non-GAAP financial measures, including, but not limited to, adjusted EBITDA, free cash flow, gross leverage ratio, and adjusted R&D, are presented in order to supplement investors' and other readers' understanding and assessment of the financial performance of Viatris Inc. ("Viatris" or the "Company"). Free cash flow refers to U.S. GAAP net cash provided by operating activities, less capital expenditures. Viatris has provided reconciliations of such non-GAAP financial measures to the most directly comparable U.S. GAAP financial measures and other readers are encouraged to review the related U.S. GAAP financial measures and the reconciliations of the non-GAAP measures to their most directly comparable U.S. GAAP measures set forth in this presentation on our website at https://investor.viatris.com/financial-information/non-gaap-reconciliations, and investors and other readers should consider non-GAAP measures only as supplements to, not as substitutes for or as superior measures to, the measures of financial performance prepared in accordance with U.S. GAAP.

#### **Key References**

New product sales, new product launches or new product revenues: Refers to revenue from new products launched in the relevant period and the carryover impact of new products, including business development, launched within the last 12 months.



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### Strategic Overview

- Viatris Durable, High-Margin Organic Pipeline
- Idorsia Collaboration
  - Selatogrel Acute Myocardial Infarction
  - Cenerimod Systemic Lupus Erythematosus
- Idorsia Transaction & Commercial Overview
- Question and Answer



Agenda

# Strategic Overview



Scott A. Smith Viatris CEO



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### Viatris at a Glance – Our Global Infrastructure



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<sup>(2)</sup> Key Facts and Figures data represents anticipated figures post-closing of all announced divestitures.

## Significant Financial Flexibility and Multiple Levers to Drive Future Growth





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For non-GAAP measures, see slide 3

### Idorsia Collaboration is an Important Step in Our Return to Growth Strategy





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# Durable, High-Margin Organic Pipeline



Rajiv Malik Viatris President



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### Strong Base R&D and Pipeline Foundation with Consistent Track Record





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### **Deep In-House Development Capabilities**

Robust Science, Pre-Clinical & Device Engineering



all of

Strong Clinical Development & Medical Affairs Across Multiple Therapeutic Areas

> Proven Regulatory, Legal & IP Skills



Novel Products ~3,700 Development, Clinical, Complex Medical, Pharmacovigilance Injectables and Regulatory Workforce Respiratory g **Development Centers Executing in Multiple** Drug Device Technology Platforms and **Development Therapeutic Areas** Topicals and **62** Transdermals Markets with in-country **Regulatory Expertise** Traditional Generics



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### Complex Injectables Pipeline – 9 FTM Potential Opportunities



57 Complex Injectable Products – Key Durable Contributor of Potential New Product Launches Over Next 5 Years



## Select Novel & Complex Products

Product	Indication	Pre-Clinical	Phase 1	Phase 2	Phase 3	Under Regulatory Review	Status	Anticipated Launch Year
Glatiramer Once Monthly	Treatment of relapsing forms of multiple sclerosis						Under Review	TBD
Meloxicam Fast Acting (Opioid Sparing)	Opioid sparing treatment in post surgery pain						Phase 3 Studies Ongoing	2027
Xulane Low Dose	Birth control/contraception						Phase 3 Study Enrollment Complete	2026
Onabotulinumtoxin A (Botox <sup>®</sup> )	Treatment of cervical dystonia, overactive bladder, glabellar lines, others						IND Enabling Studies in Process	2026
Effexor® (GAD)	Generalized Anxiety Disorder						Phase 3 Ongoing	2026
MR-130	Birth Control / Contraception						Phase 2 dose ranging study complete	TBD

### **26** Novel & Complex Products in Pipeline – Another Growth Catalyst



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# Eye Care Portfolio & Pipeline

Product	Indication	Pre-Clinical	Phase 1	Phase 2	Phase 3	Regulatory Approval	Status
Tyrvaya <sup>®</sup> (Varenicline solution)	Dry Eye Disease						Launched 10/15/21
Ryzumvi™ (phentolamine ophthalmic solution)	Reversal of Pharmacologically Induced Mydriasis						Planned Launch H1 2024
Tyrvaya <sup>®</sup> (Varenicline solution)	Dry Eye Disease (China)	NMPA Accep	oted NDA				2025
MR-146	Neurotrophic Keratopathy (Stage 2 & 3)		IND Enabling	g Studies Unde	erway		2027
MR-141	Presbyopia	Second Pha	se 3 Initiating	in Q2 2024			2026
MR-148	Dry Eye Disease	Phase 3 Initi	ated				2027
MR-139	Blepharitis	Phase 3 Initi	ating in Q2 20	24			2026
MR-142	Dim Light or Night Vision Disturbances	Phase 3 Ong	going				2026

### **\$1B+** Peak Net Sales Expected



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## Strong Base R&D and Pipeline Expected to Continue to Deliver



Expect to Deliver \$450M - \$550M Annual New Product Launches in 2024



# Idorsia Collaboration



Philippe Martin Viatris Chief R&D Officer



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# Acute Myocardial Infarction & Selatogrel



# Prof. Deepak L. Bhatt, MD, MPH, MBA Director, Mount Sinai Fuster Heart Hospital

# Selatogrel investigated for the selfadministered emergency treatment of recurrent Acute Myocardial Infarction



# Epidemiology of Acute Myocardial Infarctions (AMI)

Heart attacks can occur in: All ages, races, ethnicities, and sexes.



of deaths caused by cardiovascular disease are due to heart attack and stroke

#### **Recurring Heart Attack**

Patients with history of MI are at significantly higher risk of recurrent MI

> **9-10M** Patients in US and EU have history of AMI within past 10 years

### Major Role of Platelets in Acute MI

**Myocardial Infarction** 



Adapted from: Ferguson JJ. In: Ferguson JJ, Chronos N, Harrington RA (Eds). *Antiplatelet Therapy in Clinical Practice*. London: Martin Dunitz; 2000: 15–35.

### "Time is Muscle!" - Early Intervention is an Opportunity for Myocardial Salvage

### Early Coronary Thrombus is Platelet-rich, Early Treatment is Key



<sup>&</sup>lt;sup>1</sup>Silavail J et al JACC 2011, <sup>2</sup>Boersma et al Lancet 1996 Adapted from: Silvain J et al JACC 2020

### Dire Need for Early Intervention at Onset of Acute Myocardial Infarctions



# Multiple P2Y12 Inhibitors are Already Approved, But Only Selatogrel is Suitable for Emergency Treatment

Name	Clopidogrel	Prasugrel	Ticagrelor	Cangrelor	Selatogrel
Group	Thienopyridine	Thienopyridine	ATP-analog	ATP-analog	2-phenylpyrimidine- 4-carboxamides
Administration	Oral (qd)	Oral (qd)	Oral (bid)	Intravenous	subcutaneous
Receptor Blockdade	irreversible	irreversible	reversible	reversible	reversible
Prodrug	yes	yes	no	no	no
Suitable for subcutaneous injection	no	no	no <sup>1</sup>	no <sup>2</sup>	yes
Time to peak effect	2-6 h	2-4 h	2 h	2 min	15-30 min
Offset for effect	5-10 d	7-10 d	3-5 d	~0.5 h	~24 h
Preclinical profile					
Potency IPA (20 µM ADP	na	na	398 nM <sup>3</sup>	45 nM <sup>4</sup>	14 nM
Off-target effects	yes	yes	yes	yes	no
Efficacy/Safety window	**	**	***	***	****

ADP: Adenosine diphosphate, ATP: Adenosine triphosphate, IPA: Inhibition of platelet aggregation

<sup>1</sup> Solubility in water limited to 10 ug/ml, <sup>2</sup> Stability in aqueous solution limited to 12 h

<sup>3</sup> Nylander and Schulz, 2016, PMID: 26758983, <sup>4</sup> NDA 204958 Cangrelor

# Robust and Rapid Effect Observed in Phase 2 Program in Acute Coronary Syndrome (N=345) and Acute MI (N=47)

### Differentiated Profile vs Other P2Y12 Inhibitors



- Robust and rapid effect: >80% IPA within 15 minutes
- Short Duration: Height of IPA effect extended over 8 hours, with platelet recovery within 24 hours
- IPA was faster, more pronounced, and more consistent with 16 mg
- Effect also obtained on top of background dual anti-platelet therapy (P2Y12 inhibitor + aspirin)

Data from chronic coronary syndrome study – consistent with results from AMI study (1) DAPT: dual anti-platelet therapy

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# Selatogrel: Reduced Off-target Interference of Hemostasis Compared to Other P2Y12 Inhibitors

### No Off-Target Effects Interfering with Hemostasis due to Selatogrel High Selectivity

No activity on multiple signaling pathways (including P2Y1)<sup>(1)</sup>

Impact on key-elements of hemostasis at same anti- thrombotic effect level	Control	Selatogrel	Ticagrelor	Clopidogrel
Calcium signaling in endothelial cells	Functional	No decrease	Partial decrease	N/D
Vasoconstriction	Functional	No decrease	Partial decrease	N/D
Neutrophil adhesion	Functional	No decrease	Decrease	Decrease
Fibrin generation	Functional	No decrease	Partial decrease	Decrease
Stability of platelet-seal	Functional	No decrease	Partial decrease	Decrease

Data summarized from: Crescence et al. 2021; Rey et al. 2012
(1) No activity on 120 GPCRs (incl. P2Y1) @10 mM No effect on: ENT1, A3, PDE5, GPR17, P2Y1

### Selatogrel Causes Less Blood Loss than Ticagrelor at Equivalent Efficacy in Anesthetized Wistar Rats



Rat thrombosis model. Dose dependent surgical blood loss after standardized punch biopsy of the spleen. Drugs administered by continuous infusion to achieve low-, intermediate-, and high-level inhibition of platelet aggregation. Selatogrel doses; 0.06, 0.2, 0.6  $\mu$ g/kg/min. Ticagrelor doses; 2, 6, 20  $\mu$ g/kg/min. After surgical wounding of the spleen, blood was collected for 30 min and the weight of lost blood determined. Data are presented as means ± SEM, n = 9-35. \*P < 0.05. \*\*P < 0.01.

### Differentiated Safety Profile and No Difference in Major Bleeds Compared to Placebo on Top of Standard of Care

Treatment-emergent AEs <sup>(1)</sup> , n (%)	8 mg selatogrel (N=114)	16 mg selatogrel (N=115)	Placebo (N=116)
Patients with ≥1 AE	36 (32)	26 (23)	25 (22)
Patients with serious AEs	0	0	0
Most frequent AEs (≥3 subjects)			
Dyspnoea	6 (5)	10 (9)	0
Median duration, h	2.4	0.8	-
Dizziness	5 (4)	4 (4)	1 (1)
Headache	3 (3)	3 (3)	5 (4)
Injection site bruising	3 (3)	2 (2)	0
Diarrhea	4 (4)	1 (1)	0
Vessel puncture site bruise	4 (4)	0	3 (3)
Contusion	1 (1)	1 (1)	3 (3)
Patients with ≥1 bleeding event	11 (10)	5 (4)	8 (7)
Major bleeding events	0	0	0

Data from chronic coronary syndrome study - consistent with results from AMI study

(1) Treatment-emergent was defined as any AE occurring up to 48 h after treatment administration

# Selatogrel Has the Potential to Shift Treatment Paradigm in AMI

### Selatogrel



#### Potent, reversible and highly selective P2Y<sub>12</sub> receptor antagonist

 With reduced off target interference of hemostasis compared to other P2Y<sub>12</sub> in preclinical setting



### Rapid uptake and fast onset of action

 In phase 2 trial, > 90% of participants have > 80% inhibition of platelet aggregation (IPA) 15 minutes after dosing

### Short duration of action

 IPA effect lasted about 6 to 8 hours, with platelet recovery within 24 hours



### Suitable safety profile

 No difference in major bleeds compared to placebo on top of standard of care in phase 2 trial



### Auto Injector

# Selatogrel



Philippe Martin Viatris Chief R&D Officer



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A multi-center, double-blind, randomized, placebo-controlled, parallel-group study to evaluate the efficacy and safety of self-administered subcutaneous selatogrel for prevention of all-cause death and treatment of acute myocardial infarction in subjects with a recent history of AMI

ClinicalTrials.gov Identifier: NCT04957719





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# A Simple Design to Maximize Operational Success







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# Expansive Global Footprint for the SOS-AMI Pivotal Trial ~500 Sites across 37 Countries



Current Assumption: Full Enrollment Anticipated in 2026





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# Assumptions & Key Endpoints in SOS-AMI



Event Driven Study: ~4,500 Events Needed (Patients Treated) Relative Risk Reduction ~20%; Type I Error Set to 5%





### **Providing Tools to Empower Patients** Comprehensive Training in Phase 3





### **Recognizing heart attack symptoms**

#### **Common symptoms**

- Chest pain.
- Chest discomfort.
- Chest pressure.
- Chest tightness.
- Heaviness in the chest.
- · Burning in the chest.
- A feeling like a band around the chest or a weight on the chest.



#### What to do if you have heart attack symptoms

When you get heart attack symptoms follow these two easy steps



Think

Heart **First** 

#### Important information

- Your immediate action is the most important step in the treatment of a heart attack.
- If you have symptoms, use your study autoinjector as instructed and call 911 or get emergency medical help right away. Don't wait longer than 15 minutes to act.
- Always call 911 or get emergency medical help right away because this is the fastest way to get further care. Any other action may delay treatment.
- Even if it is not a heart attack, you are doing the right thing by calling 911 or getting emergency medical help.



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### What We Have Observed So Far from SOS-AMI Pivotal Trial Approximately 6,000 Patients Randomized to Date



Principle of self-administration upon recognition of heart-attack symptoms is well accepted by the patients

Patients are injecting early (i.e., very close to symptom onset)

Patients are able to inject for the right reason (i.e., chest symptoms suggestive of an AMI)





Unblinded Independent Data Monitoring Committee (IDMC): met 6 times since start of the study and recommended to continue the study as planned


### Selatogrel is a Highly-Innovative First and Only Self-Administered Treatment for Acute Myocardial Infarction (AMI)

Criteria	Selatogrel Overview
Unmet Need / Market Potential	<ul> <li>High disease burden in AMI which accounts for 1/3 of deaths in developed nations with annual incidence of ~2M in US and EU</li> <li>Dire need for early intervention at onset of AMI symptoms as ~30% of deaths occur prior to hospital admission</li> <li>Selatogrel has the potential to shift treatment paradigm in AMI with early intervention</li> </ul>
Validated Mechanism	<ul> <li>P2Y12 is a well-established target with approved dual-antiplatelet therapies used in chronic settings</li> <li>Time is muscle – early coronary thrombus is platelet-rich, early treatment is key</li> </ul>
Proof of Concept	<ul> <li>Differentiated safety and efficacy profile demonstrated by phase 2 data supports Selatogrel's use in self-administered emergency treatment of recurrent AMI</li> </ul>
Path to Approval & Beyond	<ul> <li>Comprehensive phase 3 study design with Special Protocol Assessment agreed with FDA and fast track designation – full enrollment expected in 2026</li> <li>LCM indications can significantly increase Selatogrel addressable population</li> </ul>



## Systemic Lupus Erythematosus & Cenerimod



Dr. Anca Askanase, MD Founder & Clinical Director, Columbia University's Lupus Center

# Cenerimod investigated for the treatment of patients with systemic lupus erythematosus (SLE)



# High Unmet Need for New Approaches in the Treatment of Systemic Lupus Erythematosus (SLE)



- Lupus can range from mild to severe depending on how it affects the body
- Limited treatment options with a high need for new approaches
- Despite the existence of several therapeutic agents in SLE, the disease keeps causing significant morbidity



Mild joint and skin problems, tiredness



#### Moderate

inflammation of other parts of the skin and body, including the lungs, heart, and kidneys



#### Severe

inflammation causing severe damage to the heart, lungs, brain, or kidneys, which can be life threatening

### Limitations of Current SLE Treatments

Antimalarial Drugs	<ul> <li>Hydroxychloroquine to manage skin and joint symptoms, and reduce flare frequency</li> <li>Associated with retinal toxicity</li> </ul>
Corticosteroids	<ul> <li>Prednisone (among others) to control flares</li> <li>Long-term use is associated with hypertension, hyperglycemia, Cushing syndrome, etc.</li> </ul>
Immunosuppressants	<ul> <li>Methotrexate, azathioprine, and mycophenolate mofetil to regulate / suppress the immune system</li> <li>Infections and malignancy risk are the main limitations</li> </ul>
Biologics	<ul> <li>Belimumab (first FDA-approved biologic specifically for SLE in 2011), Rituximab (used off-label for certain cases with severe manifestations), and Anifrolumab (FDA-approved in 2021)</li> <li>Premedication is needed for IV infusion, associated with lack / loss of efficacy and risk of anaphylaxis, increased risk of serious and fatal infections, increased malignancy risk</li> </ul>

### Cenerimod Acts on the Three Main Pillars of SLE Pathogenesis



References: Strasser DS, RMD Open. 2020. PMID: 32917831; Gerossier E, Arthritis Res Ther. 2021. PMID: 34839819; Hermann V, Lupus Sci Med. 2019. PMID: 31798918; Askanase A, Arthritis Rheumatol. 2022;74(suppl 9):3293–7; Strasser DS, Arthritis Rheumatol. 2022;74(suppl 9):1981-2; Hoyler T, Lupus Science & Medicine. 2023. Abstract 2023-0588 Burg N et al. Nature Review Rheumatology 2022, 18

# Cenerimod Targets More SLE Pathological Pathways than Any Other Recent Therapies

Compound	Mechanism	Mechanism of Action	Targets		
Compound	of Action	Effects	T-cells	B-cells	Type I IFN
Cenerimod	S1P1 receptor modulator	Inhibits the egress of autoreactive T- and B-cells, reduces pro- inflammatory cytokines (incl. Type-1 IFN) and chemokines and prevents migration of antigen-presenting cells			
Benlysta® (belimumab)	B-Lymphocyte stimulator (BLyS) inhibitor	Reduces the survival of B cells, especially autoreactive B cells that produce antibodies			
Saphnelo® (anifrolumab)	IFN receptor antagonist	Reduces Type-1 IFN signaling			
Rituximab	Anti-CD20 mAb	Causes B cell depletion			

### Cenerimod Unique in S1P Receptor Modulator Class



- Potent selective S1P1 modulator
- Oral, once-a-day
- Unique signaling properties (biased Ca++ signaling) allowing:
  - Absence of vasoconstriction
  - Decreased bronchoconstriction
- Cenerimod progressive increase in exposure = gradual desensitization of the cardiac S1P receptors = mitigating cardiovascular manifestations
  - No need for up-titration to manage Heart Rate upon treatment initiation





### **Cenerimod Studies**

#### Over 700 Subjects Treated with Cenerimod to Date in Phase 1 & 2 and Ongoing Pivotal Studies

Phase 1	Phase 2	Phase 3
~200 clinical research volunteers (CRV)	407 patients with SLE exposed to cenerimod in three completed clinical studies	>100 patients with SLE enrolled in ongoing study
<ul> <li>SAD, 24 CRV: studied doses up to 25mg; MTD 10mg</li> <li>MAD, 24 CRV: Studied doses up to 4mg; MTD not reached</li> </ul>	<ul> <li>AC-064A201, 67 patients: safety, tolerability, PD and PK of cenerimod 0.5, 1, 2, and 4 mg vs placebo in SLE patients (12 weeks)</li> <li>ID-064A202 (CARE), 427 patients: efficacy, safety, and tolerability of</li> </ul>	
	cenerimod 0.5, 1, 2, and 4 mg vs placebo in moderate/severe SLE patients (12 months)	
	<ul> <li>ID-064A203, 17 patients: safety and tolerability of cenerimod 2 and 4 mg in Japanese moderate/severe SLE patients (3 months)</li> </ul>	

### Phase 2 CARE: Study Design

Primary Objective

Investigate Disease Activity Reduction with Cenerimod after 6 Months at 4 Different Doses (0.5, 1, 2, and 4 mg) in Subjects with Moderate to Severe SLE on Top of Standard of Care



### Phase 2 CARE: Baseline Demographics & Disease Characteristics

#### Baseline Demographics & Disease Characteristics Well-balanced across All Treatment Groups

Baseline characteristics	Overall population n=427
Age, mean ± SD	41.6 ± 11.9
Female, n (%)	406 (95.1)
Race – White, n (%)	337 (78.9)
Background SLE treatment, n (%)	
Corticosteroids	366 (85.7)
Antimalarials	314 (73.5)
Immunosuppressives	155 (36.3)
Biologics (belimumab)	13 (3.0)
mSLEDAI-2K, mean ± SD	9.9 ± 3.0
IFN-1 High %	51%

Moderate to severe SLE patients with multiple concomitant SLE treatments

### Cenerimod 4mg Demonstrated Statistically Significant<sup>(1)</sup> and Clinically Meaningful Response in Phase 2 Trial



Full Analysis Set

(1) Nominally statistically significant due to the testing strategy (for adjusting for multiplicity of tests of the 4 doses against placebo)

(2) SLE disease activity index 2000 (SLEDAI-2K) modified to exclude leukopenia

### SRI-4 Response was Consistent with mSLEDAI-2K Secondary Endpoint



SRI-4 response<sup>(1)</sup> at 6 months (%)

SRI-4 response<sup>(1)</sup> at 6 months (%)

69.7%

(n=33)

Full Analysis Set

(1) SRI-4 response is defined as a response of all three components: mSLEDAI-2K (reduction from baseline  $\geq$ 4), Physicians Global Assessment (increase from baseline ≤0.3), BILAG-2004 (no new BILAG A organ domain score and ≤1 new BILAG B organ domain score)

# Phase 2 CARE Population Had an Under-Representation in % of IFN-1 High Patients Compared to Other Programs

Drug	IFN-1 High (%)	Study	Source
Anifrolumab	83%	Phase 3 – Tulip-1/2	Furie / Morand 2019
Anifrolumab	75%	Phase 2 – MUSE	Furie 2017
Belimumab	83%	BLISS-52/76	Wilkinson 2020
Cenerimod	51% <b>(4mg arm 45%)</b>	Phase 2 – CARE	Idorsia

- ► IFN-1 high typically believed to represent ~70-80% of moderately to severe SLE patients<sup>(1)</sup>
- IFN-1 high status is associated with indicators of more active and severe disease:
  - Higher levels of anti-dsDNA, and lower levels of C3 & C4
  - Arthritis & skin disease
  - Proteinuria and increased risk of progression to lupus nephritis

<sup>(1)</sup> CARE manuscript submitted and under review

### Phase 2 CARE: Cenerimod Treatment Effect Consistently Increased in More Severe Patients vs. the Overall Population



# Phase 2 CARE: Low Rates of AEs and SAEs, Generally Similar Across Treatment Groups

#### **Onset During 6-Month Treatment**

Subjects with at least one	Cenerimod 0.5 mg N=85 n (%)	Cenerimod 1 mg N=85 n (%)	Cenerimod 2 mg N=86 n (%)	Cenerimod 4 mg N=84 n (%)	Placebo N=86 n (%)
Adverse Event (AE)	42 (49.4)	55 (64.7)	51 (59.3)	49 (58.3)	47 (54.7)
AE leading to study drug discontinuation	1 (1.2)	3 (3.5)	9 (10.5)	8 (9.5)	4 (4.7)
Serious adverse event	0	3 (3.5)	2 (2.3)	2 (2.4)	3 (3.5)
Fatal AE	0	1 (1.2)	0	0	0
Adverse Events >5% <sup>(1)</sup>					
Lymphopenia	1 (1.2)	4 (4.7)	9 (10.5)	12 (14.3)	1 (1.2)
Hypertension <sup>(2)</sup>	2 (2.4)	4 (4.7)	1 (1.2)	5 (6.0)	2 (2.3)
Headache	9 (10.6)	5 (5.9)	7 (8.1)	7 (8.3)	3 (3.5)
Abdominal pain	1 (1.2)	5 (5.9)	0	2 (2.4)	0
COVID-19	5 (5.9)	0	5 (5.8)	2 (2.4)	2 (2.3)

(1) >5% in any group and higher than placebo.

(2) Hypertension: Most subjects with AEs denoting hypertension had a medical history of hypertension and/or were receiving corticosteroids; monthly BP measurements showed no increases in mean systolic or diastolic blood pressure; hypertension did not lead to discontinuation or temporary interruption of study drug in any subjects.

### Adverse Events of Special Interest: Overall Mild and Transient

#### **Onset During 6-Month Treatment**

Category / Preferred Term	Cenerimod 0.5 mg N=85 n (%)	Cenerimod 1 mg N=85 n (%)	Cenerimod 2 mg N=86 n (%)	Cenerimod 4 mg N=84 n (%)	Placebo N=86 n (%)
Effect on HR and rhythm-related AEs	2 (2.4)	1 (1.2)	4 (4.7)	4 (4.8)	1 (1.2)
Infection-related AEs	8 (9.4)	3 (3.5)	7 (8.1)	3 (3.6)	8 (9.3)
Pulmonary-related AEs	1 (1.2)	3 (3.5)	2 (2.3)	3 (3.6)	2 (2.3)
Hepatobiliary disorders / liver enzyme abnormality-related AEs	2 (2.4)	4 (4.7)	2 (2.3)	1 (1.2)	0
Malignancy (non-skin) related AEs	0	0	0	0	1 (1.2)
Malignancy (skin) related AEs	0	0	0	0	0

Heart Rate and rhythm: Day 1 cardiovascular monitoring revealed no unexpected finding or concern at any dose

- No second-degree or higher AV blocks were observed
- No increased incidence of medically relevant bradycardia or rhythm-related AEs over 6-months
- Macular Edema: one subject in the 1mg group was reported with macular edema adjudicated by the Ophthalmology Safety Board as not related to cenerimod as the event was already present at screening

# Cenerimod



Philippe Martin Viatris Chief R&D Officer



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### **Comprehensive Phase 2 Program Conducted in SLE**



- 407 patients with SLE exposed to cenerimod in three completed P2 clinical studies
- Robust and consistent phase 2 data:
  - Efficacy results consistent across all three phase 2 studies
  - Higher response observed in expected phase 3 population (more severe patients)
  - Treatment effects continue to increase over time
  - Differentiated safety profile versus existing SLE treatments



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### Cenerimod Has Highly Competitive Efficacy Profile vs Other Phase 2 or Approved Treatments





### Cenerimod Has an Optimized S1P Safety Profile that Compares Favorably vs Approved SLE Treatments



First dose effect: HR reduction comparable to other S1P modulators but no need for up-titration; no unexpected finding or concern at any dose in phase 1 MAD and phase 2 studies



Echocardiography and Holter: no clinically meaningful effect observed



No increased risk of infections and opportunistic infections, malignancy, macular edema, liver enzyme elevations (compared to placebo)



No clinically meaningful effect on pulmonary function and blood pressure

Treatment with Cenerimod was **not associated with an increased risk of Serious Adverse Events and infection**, a major concern to physicians and patients

associated with rse Events and tians and patients	Cenerimod ★ CARE Phase 2		Soty (Deucrav Pha	Sotyktu (Deucravacitinib) Phase 2		Saphnelo (Anifrolumab) Phase 2	
	4 mg (N=84)	Placebo (N=86)	3 mg bid (N=91)	Placebo (N=90)	300 mg (N=99)	Placebo (N=101)	
Overall AEs (%)	78.6	70.9	93.4	87.8	84.8	77.2	
nfections (%)	33.3	36.0	65.9	53.3	69.7*	55.4*	
Serious AEs (%)	3.6	7.0	7.7	12.2	18.8	16.2	

\*Pooled safety DB (ph2 + ph3), 52-weeks







### **OPUS: Confirmatory Pivotal Program Design**



Two Phase 3 multicenter, randomized, double-blind, placebo-controlled, parallel-group studies to evaluate the **efficacy**, **safety**, and **tolerability** of cenerimod in adult patients with moderate-to-severe SLE on top of background therapy<sup>(1)</sup>



(1) Includes antimalarial, OCS, immunosuppressant and Benlysta



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### Expansive Global Footprint for the OPUS Pivotal Studies OPUS Program to Recruit 840 Patients in ~25 Countries and ~340 Sites



#### >100 Patients Enrolled to Date and Recruitment Completion Planned for End of 2025





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### Pivotal Studies Key Features – Designed to Maximize Treatment Effect Based on Learnings from Phase 2



	Difference in study design between CARE and OPUS	Rationale based on CARE findings and HAs feedback		
Design	Two adequate and well controlled studies with 840 patients (420 per study)	Study powered for type I error of 5% (p <0.05) study powered for key secondary endpoints		
Population	<ul> <li>IFN-1 high (75 to 85%)</li> <li>BILAG 1A and/or 2B</li> <li>PGA ≥ 1.0 on a 0 to 3 VAS</li> <li>EGFR: include severely impaired patients</li> <li>Anti-Smith (anti-Sm) antibody elevated to above normal</li> </ul>	Enriched responder population vs CARE to maximize treatment effect		
Primary Endpoint	SRI-4 response	<ul> <li>24% more SRI-4 responders with cenerimod 4 mg than placebo in IFN-1 High population</li> <li>Regulatory precedent and supported by both FDA and EMA at EOP2 meeting</li> </ul>		
Timing of Primary Endpoint	12 months	Cenerimod maximum treatment effect (delta vs placebo) expected by 12 months		
Oral Corticosteroids	Forced tapering	Allow detection of OCS sparing – maximize treatment effect (if tapering not achieved patients are considered non-responder)		



### Cenerimod is a First-In-Class Oral Therapy with Novel MoA and Potential for Highly Differentiated Benefit-Risk Profile in SLE

Criteria	Cenerimod Overview
Unmet Need / Market Potential	<ul> <li>Systemic lupus erythematosus (SLE) is a chronic and progressive autoimmune disease affecting 3.4M patients globally with limited treatment options and significant morbidity</li> </ul>
Validated Mechanism	<ul> <li>Cenerimod is a novel S1P<sub>1</sub> antagonist with unique mechanism of action (MoA), tackling multiple aspects of lupus pathogenesis</li> </ul>
Proof of Concept	<ul> <li>Robust and consistent phase 2 data showed highly differentiated safety and efficacy profile vs other approved or phase 3 drugs</li> <li>Clinically meaningful response observed in phase 2; higher response observed in more severe patients expected to be more consistent with the phase 3 population</li> <li>Treatment effects continue to increase over time, with differentiated safety profile</li> <li>Efficacy results consistent across all phase 2 studies, including Japanese study</li> </ul>
Path to Approval & Beyond	<ul> <li>Two comprehensive phase 3 studies ongoing, designed in collaboration with Health Authorities and the medical community, and reflecting learnings from phase 2 studies – full enrollment expected end of 2025</li> <li>Adequate and well-controlled studies with enriched population to maximize treatment effect</li> <li>FDA fast track designation</li> <li>Cenerimod's MoA is optimally suited for multiple indication expansion opportunities beyond SLE</li> </ul>



# Idorsia Transaction & Commercial Overview



Doretta Mistras Viatris CFO



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### Idorsia Collaboration Expands Our Portfolio of Innovative Assets and Potentially Accelerates Long-Term Growth

Foundational Assets to Drive Long-Term Growth	<ul> <li>Highly novel and differentiated target product profiles with large addressable markets leading to blockbuster potential</li> <li>Exclusivity potentially into the 2040's provides runway for additional LCM opportunities</li> </ul>
Favorable Deal Structure	<ul> <li>Upfront payment secures commercial rights to two phase 3 assets</li> <li>Milestones tied to success-based regulatory and commercial events</li> <li>Flexible opt-ins to access promising pipeline</li> </ul>
Attractive Risk-Reward	<ul> <li>Asymmetric risk and return profile to drive strong value creation for shareholders</li> <li>Manageable near-term and long-term P&amp;L impact</li> </ul>
Delivers on Our Return to Growth Strategy	<ul> <li>Evolving portfolio mix to more durable, higher-margin assets</li> <li>Opportunity to accelerate long-term revenue and earnings growth</li> <li>R&amp;D collaboration establishes foundation and adds scientific expertise for innovation engine</li> </ul>



### Selatogrel: Highly Innovative Treatment with Blockbuster Revenue Potential

Significant Market of Patients with Life-Threatening Events	Game Changing Profile Fulfills Significant Unmet Need	Attractive Commercial Dynamics
<ul> <li>Large worldwide population <ul> <li>24M+ post-AMI patients</li> <li>2M+ new AMI cases annually</li> </ul> </li> <li>30%-40% mortality before receiving hospital treatment</li> <li>Currently no approved treatments for the time of symptom onset</li> </ul>	<ul> <li>Targets the most critical phase of AMI to deliver more time and improved care</li> <li>Potential for compelling morbidity and mortality advantage can drive adoption and value</li> <li>Capacity to be integrated into current standard of care</li> </ul>	<ul> <li>Lifelong patients with continuous need for access to "on-demand" treatment</li> <li>Broad policy, advocacy and patient education experience</li> <li>Extensive channel and distribution capabilities</li> <li>Exclusivity potentially into 2040's</li> </ul>
Potential for AMI survivors to become lifelong Selatogrel patients	Opportunity for <b>first and only patient</b> <b>administered</b> AMI treatment	Demonstrated <b>leadership</b> in patient administered <b>rescue medications</b>



# Selatogrel: Near-Term Blockbuster Revenue Potential with Multiple Expansion Opportunities

Potential Blockbuster	Additional Reven	ue Opportunities	•
Post-AMI	High-Risk CVD, Pre-AMI	Transient Ischemic Attack	
<ul> <li>Represents prevalent and annual incident cases</li> </ul>	<ul> <li>Patients with high cardiovascular risk factors</li> <li>&gt;10% US population with a &gt;20% CV Risk Score</li> </ul>	<ul> <li>Patients with history of TIA have risk of recurrent TIA</li> </ul>	

#### **Worldwide Prevalence**





### Cenerimod: Highly Innovative Treatment with Blockbuster Revenue Potential

Large Established Addressable Patient Population	Novel Differentiated Mechanism of Action	Attractive Commercial Dynamics
<ul> <li>~5M people worldwide living with a form of lupus</li> <li>Progressive disease with limited and harsh treatment options</li> </ul>	<ul> <li>First in class S1P1 therapy in SLE</li> <li>Attractive oral, once daily immunomodulator profile</li> <li>Potential to lower disease activity in addition to standard therapies</li> </ul>	<ul> <li>Well defined and succinct group of specialized prescribers</li> <li>Opportunity to be positioned prior to biologics</li> <li>Exclusivity potentially into 2040's</li> </ul>
High unmet need for new safe and tolerable options to add onto existing therapies	Potential for <b>highly differentiated</b> <b>benefit / risk profile</b> compared to current treatments	Rheumatic condition with unique value dynamics



### Cenerimod's MoA is Optimally Suited to Target Multiple Autoimmune & Inflammatory Diseases

**Potential Blockbuster Additional Revenue Opportunities** Systemic Lupus Indications with Diseases Linked to Lupus **Rheumatic Diseases** Approved S1P1 Therapies Erythematosus ~50% of treated SLE patients Label expansion de-risked with Large, fragmented market with Clinical validation in multiple have moderate and severe SLE potential SLE approval and potential opportunity with highly prevalent autoimmune clinical data differentiated clinical profile diseases **Worldwide Prevalence 3.4m** +4.9m +30.9m **Multiple Sclerosis Lupus Nephritis Psoriatic Arthritis Systemic Lupus Crohn's Disease CNS Lupus Ankylosing Spondylitis Erythematosus** 

**Rheumatoid Arthritis** 

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Sjögren's Syndrome

**Ulcerative Colitis** 

Key Takeaways  Significant Financial Flexibility and Uniquely Positioned with Multiple Levers to Drive Future Growth

 Strong Base Business with Durable, High-Margin Organic Pipeline

 Idorsia Collaboration is an Important First Step in Expanding the Portfolio as Part of Our Return to Growth Strategy



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# GAAP / Non-GAAP Reconciliations

Viatris Inc. and Subsidiaries | Reconciliation of Non-GAAP Financial Measures (Unaudited; in millions) Net (Loss) Earnings to Adjusted EBITDA

	Ye	ar Ended
	December 31, 2023	
U.S. GAAP net (loss) earnings	\$	54.7
Add / (deduct) adjustments:		
Income tax (benefit) provision		148.2
Interest expense (a)		573.1
Depreciation and amortization (b)		2,740.5
EBITDA	\$	3,516.5
Add / (deduct) adjustments:		
Share-based compensation expense		180.7
Litigation settlements and other contingencies, net		111.6
Loss (gain) on divestitures of businesses		239.9
Impairment of goodwill related to assets held for sale		580.1
Restructuring, acquisition and divestiture related and other special items (c)		495.3
Adjusted EBITDA	\$	5,124.1

(a) Includes amortization of premiums and discounts on long-term debt.

(b) Includes purchase accounting related amortization.

(c) See items detailed in the Reconciliation of U.S. GAAP Net (Loss) Earnings to Adjusted Net Earnings within our Q4/FY 2023 Earnings presentation.



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### Viatris Inc. and Subsidiaries | Reconciliation of Non-GAAP Financial Measures (Unaudited; in millions) Free Cash Flow

	Ye	ar Ended	
	Decen	ember 31, 2023	
U.S. GAAP net cash provided by operating activities	\$	2,799.6	
Less: Capital expenditures		(377.0)	
Free cash flow	\$	2,422.6	



Viatris Inc. and Subsidiaries | Reconciliation of Non-GAAP Financial Measures (Unaudited; in millions, except ratio) Gross Leverage - Debt to Adjusted EBITDA

	Y	ear Ended
	Dece	ember 31, 2023
Adjusted EBITDA	\$	5,124.1
Reported debt balances:		
Long-term debt, including current portion		18,122.8
Short-term borrowings and other current obligations		-
Total		18,122.8
Add / (deduct):		
Net premiums on various debt issuances		(536.9)
Deferred financing fees		30.2
Total debt at notional amounts	\$	17,616.1
Gross debt to adjusted EBITDA		3.4 x

#### Long-term Gross Leverage Target

The stated forward-looking non-GAAP financial measure of long-term gross leverage target of 3.0x, with a range of 2.8x – 3.2x, is based on the ratio of (i) targeted notional gross debt and (ii) targeted Adjusted EBITDA. However, the Company has not quantified future amounts to develop this target but has stated its goal to manage notional gross debt and adjusted EBITDA over time in order to generally maintain or reach the target. This target does not reflect Company guidance.


## Viatris Inc. and Subsidiaries | Reconciliation of Non-GAAP Financial Measures (Unaudited; in millions, except %s) Adjusted R&D

	Year Ended December 31,			
	2020	2021	2022	2023
U.S. GAAP R&D \$	555.1 \$	751.1 \$	662.2 \$	805.2
Deduct:				
Acquisition and divestiture-related costs	(1.7)	(12.6)	(11.9)	(11.9)
Restructuring and related costs	(0.3)	(13.3)	(1.4)	(0.3)
Share-based compensation expense	(2.3)	(4.4)	(5.6)	(5.4)
SG&A and R&D TSA reimbursement (a)	-	-	(4.3)	(32.3)
Other special items	(47.2)	(83.2)	(1.0)	(2.8)
Adjusted R&D	503.6 \$	637.6 \$	638.0 \$	752.5
Total Revenues \$	11,946.0 \$	17,886.3 \$	16,262.7 \$	15,426.9
Adjusted R&D as % of total revenues	4 %	4 %	4 %	5 %

(a) Expenses related to TSA services provided to Biocon Biologics are recorded in their respective functional line item; however, reimbursement of those expenses plus the mark-up is included in other (income) expense, net. For comparability purposes, amounts related to the cost reimbursement are reclassified to adjusted SG&A and adjusted R&D. This reclassification has no impact on adjusted net earnings or adjusted EBITDA.

