SANOFI

# Q1 2019 Results

April 26, 2019

# Forward looking statements

This presentation contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future financial results, events, operations, services, product development and potential, and statements regarding future performance. Forward-looking statements are generally identified by the words “expects”, “anticipates”, “believes”, “intends”, “estimates”, “plans” and similar expressions. Although Sanofi’s management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Sanofi, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include among other things, the uncertainties inherent in research and development, future clinical data and analysis, including post marketing, decisions by regulatory authorities, such as the FDA or the EMA, regarding whether and when to approve any drug, device or biological application that may be filed for any such product candidates as well as their decisions regarding labelling and other matters that could affect the availability or commercial potential of such product candidates, the absence of guarantee that the product candidates if approved will be commercially successful, the future approval and commercial success of therapeutic alternatives, Sanofi’s ability to benefit from external growth opportunities, to complete related transactions and/or obtain regulatory clearances, risks associated with intellectual property and any related pending or future litigation and the ultimate outcome of such litigation, trends in exchange rates and prevailing interest rates, volatile economic conditions, the impact of cost containment initiatives and subsequent changes thereto, the average number of shares outstanding as well as those discussed or identified in the public filings with the SEC and the AMF made by Sanofi, including those listed under “Risk Factors” and “Cautionary Statement Regarding Forward-Looking Statements” in Sanofi’s annual report on Form 20-F for the year ended December 31, 2018. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

# Agenda

| | | |
|---|---|---|
| **Key Highlights** | Olivier Brandicourt | Chief Executive Officer |
| **Financial Results** | Jean-Baptiste de Chatillon | Executive Vice President, Chief Financial Officer |
| **Q&A Session** | Olivier Charmeil | Executive Vice President, China and Emerging Markets |
| | Karen Linehan | Executive Vice President, Legal Affairs and General Counsel |
| | David Loew | Executive Vice President, Sanofi Pasteur |
| | Alan Main | Executive Vice President, Consumer Healthcare |
| | John Reed | Executive Vice President, Global Head of R&D |
| | Bill Sibold | Executive Vice President, Sanofi Genzyme |
| | Dieter Weinand | Executive Vice President, Primary Care |

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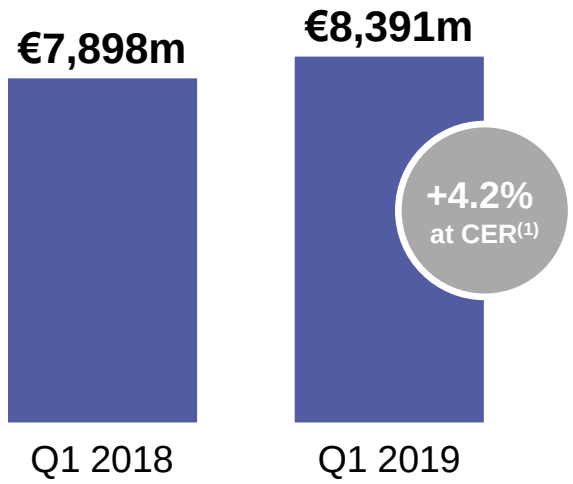
# Key highlights

**Olivier Brandicourt**

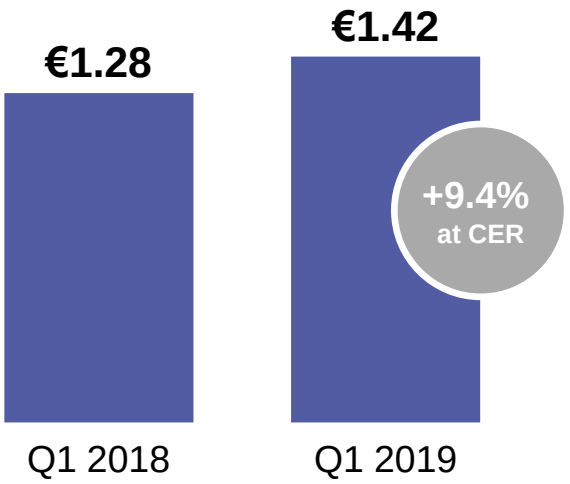
Chief Executive Officer

# Sanofi continued its return to growth in Q1 2019 with sales increase of 4.2% and EPS growth of 9.4% at CER

## Company sales



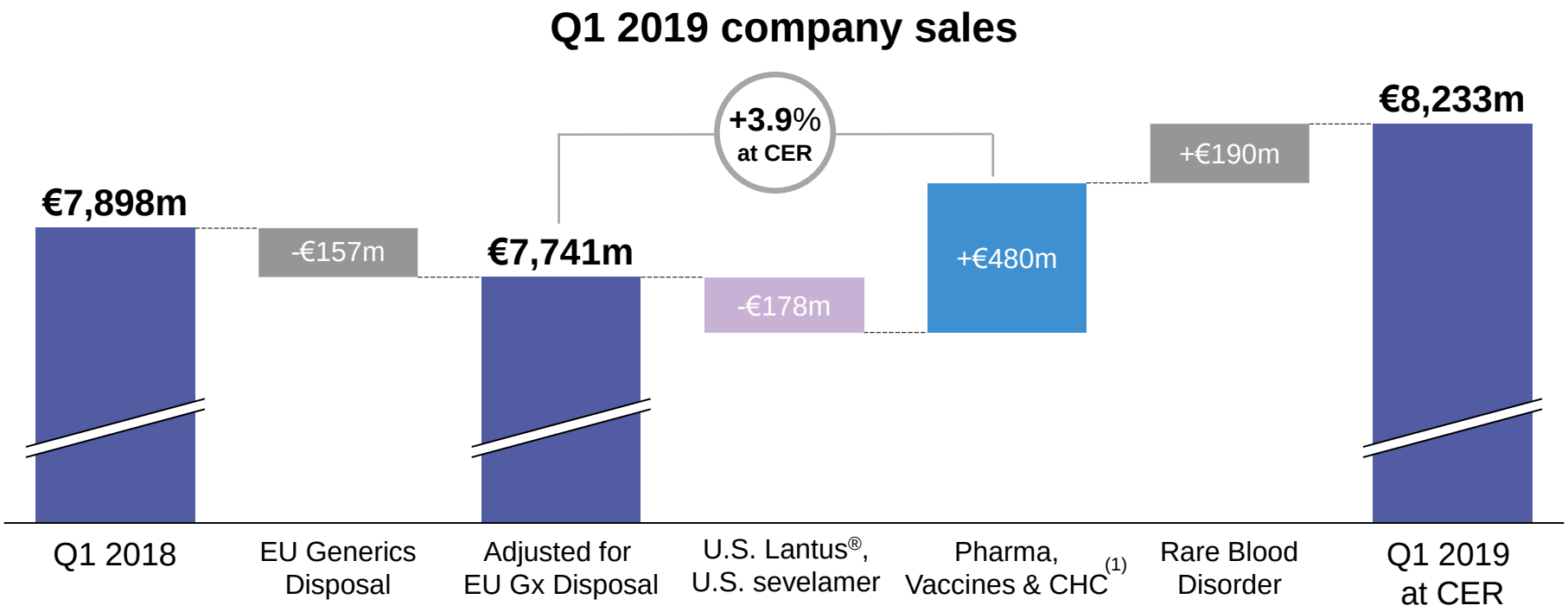

## Business EPS




CER: Constant Exchange Rates

(1) Q1 2019 sales increased +3.8% at CER/CS; Constant Structure adjusting for Bioverativ acquisition and disposal of EU Generics business

# Sales growth in Q1 2019 supported by launches and diminishing impact from LoEs in the U.S.




CER: Constant Exchange Rates; Gx: Generic; LoE: loss of exclusivity
(1) Excludes U.S. Lantus®, U.S. sevelamer and Rare Blood Disorder franchise

# Double-digit growth in 3 GBUs partially offset by lower sales of Diabetes and Established Products in Primary Care

## Q1 2019 sales by Global Business Unit

| | | Growth at CER/CS[1] |
|---|---|---|
| **Company Sales** | **€8,391m** | +3.8% |
| **Sanofi Genzyme (Specialty Care)**[2] | **€2,019m** | +16.0%[3] |
| **Sanofi Pasteur (Vaccines)**[5] | **€873m** | +20.1% |
| **Primary Care**[4] | **€2,285m** | -11.8% |
| **Consumer Healthcare**[5] | **€1,256m** | +0.6% |
| **China & Emerging Markets**[6,7,8] | **€1,958m** | +10.3% |

CER: Constant Exchange Rates; CS: Constant Structure

(1) Growth at Constant Exchange Rates and Constant Structure adjusting for Bioverativ acquisition (consolidated from March 9, 2018) and disposal of EU Generics business
(2) Does not include Emerging Markets sales; Includes Bioverativ Products
(3) At CER growth was +30.8%, including €270m in sales from Rare Blood Disorders
(4) Includes Diabetes, Cardiovascular and Established Products sales in Mature Markets
(5) Includes sales in Emerging Markets
(6) Includes Emerging Markets sales for Specialty Care, Primary Care and Established Products
(7) Emerging Markets: World excluding U.S., Canada, Western & Eastern Europe (except Eurasia), Japan, South Korea, Australia, New Zealand and Puerto Rico
(8) Excludes global Consumer Healthcare and Vaccines sales

# Strong performance in Emerging Markets across franchises; Primary Care and CHC sales down in Mature Markets in Q1

## Q1 2019 sales by geography

| | Specialty Care | Primary Care | Vaccines | Consumer Healthcare | Total sales Growth at CER/CS |
|---|---|---|---|---|---|
| **Global Sales** | **€2,327m** +18.3% | **€3,935m** -4.7% | **€873m** +20.1% | **€1,256m** +0.6% | **€8,391m** +3.8% |
| **Mature Markets** | **€2,019m** +16.0% | **€2,285m** -11.8% | **€524m** +5.7% | **€833m** -3.0% | **€5,661m** -0.6% |
| **Emerging Markets** | **€308m** +33.6% | **€1,650m** +6.6% | **€349m** +48.3% | **€423m** +8.1% | **€2,730m** +13.6% |

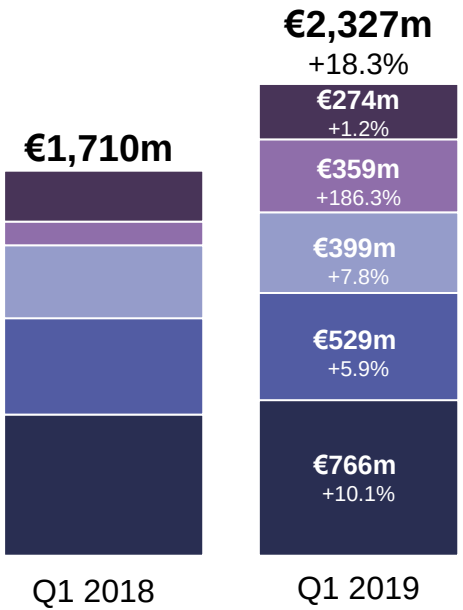
**China & Emerging Markets GBU**

**New GBU structure enables stronger organizational focus**

CER: Constant Exchange Rates; CS: Constant Structure

# Specialty Care delivered another record quarter in Q1 despite competitive dynamics in hemophilia

## Specialty Care Sales evolution




**Rare Blood Disorder**
Canada tender loss and U.S. competition affected growth in hemophilia

**Immunology**
Strong Dupixent® sales driven by adult AD and launch in asthma

**Oncology(1)**
Sustained franchise growth due to performance of legacy brands (+8%)

**Multiple Sclerosis**
Double-digit growth of Aubagio® maintained in Q1 (+12%)

**Rare Disease**
Strong growth driven by Pompe (+11%), Gaucher (+10%) and Fabry (+6%)



All growth at Constant Exchange Rates and Constant Structure adjusting for Bioverativ acquisition
(1) Sanofi does not consolidate U.S. sales of Libtayo®

# Launch update on first-in-class therapies in Specialty Care

## Rare Blood Disorder

Cablivi® caplacizumab-yhdp

First therapeutic approved for aTTP in the EU and U.S.

aTTP mortality rate of up to 20% with current standard of care(1)

- U.S. launch on April 2nd with patients treated
- Cablivi® Patient Solutions access program
- Q1 sales in Germany and France of €5m
- Cablivi® EU country launches continue
  - Recently launched in Denmark and Austria
  - Other Nordic countries planned for 2019

## Oncology

LIBTAYO® (cemiplimab-rwlc) Injection 350 mg (2)

First and only FDA approved therapy for CSCC

~7,000 patients die annually in the U.S. from CSCC

- U.S. launch focusing on medical oncologists
- Favorable coverage ensures patient access
- Approved in Brazil on March 25th and in Canada on April 10th
- EMA approval decision expected in Q2 2019
- Phase 3 adjuvant trial to start in mid-2019

CSCC: Cutaneous Squamous Cell Carcinoma; aTTP: Acquired Thrombotic Thrombocytopenic Purpura

(1) Benhamou, Y. et al., Haematologica 2012

(2) Net product sales recorded by Regeneron

# Dupixent® impressive launch continued in Q1 due to unmet need and best-in-class profile in approved indications

DUPIXENT® (dupilumab)

**Pipeline in a product**

### AD adults

- Positive real world patient experience drives uptake
- Deeper penetration with 45% of U.S. HCPs writing ≥ 4 Rx's
- Ex-U.S. launches outperforming psoriasis biologic analogues

### Asthma

- ~75% of Dupixent® U.S. asthma patients are naïve to biologics
- 90% of U.S. commercial lives covered within the first 5 months
- Positive CHMP decision in EU, launched in Japan

### AD adolescents

- U.S. launch March 11th, 2019
- U.S. population is ~1/2 size of adult AD patient population
- Significant disease burden results in high patient demand

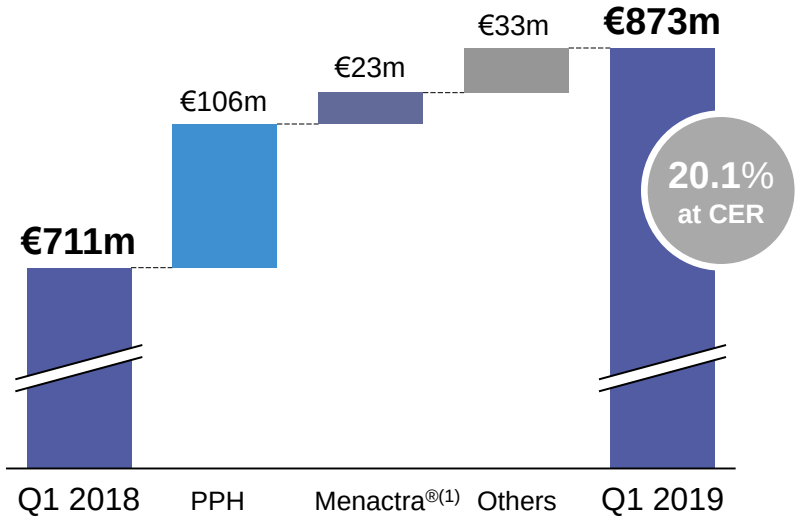
**Global Q1 Dupixent® sales €329m**

AD: Atopic Dermatitis; Rx: prescription; CHMP: Committee for Medicinal Products for Human Use; HCPs: healthcare providers
Dupixent® is in collaboration with Regeneron

# Robust Vaccines growth in Q1 driven largely by pediatric portfolio and Menactra® in emerging markets

- Vaccines sales of €873m, up 20.1%
- PPH vaccines sales grew 26% to €486m
  - China sales: €75m, +208% due to recovery and growth of Pentaxim®
  - Other EM: +31% due to expansion in public markets
  - Japan sales: €62m, +93% due to order phasing
- Menactra® sales of €112m up 21% reflecting continued strong performance in the Middle East
- Travel and endemic sales of €119 up 14% driven by Rabies vaccine sales in U.S. and Europe

## Q1 2019 Vaccines sales evolution



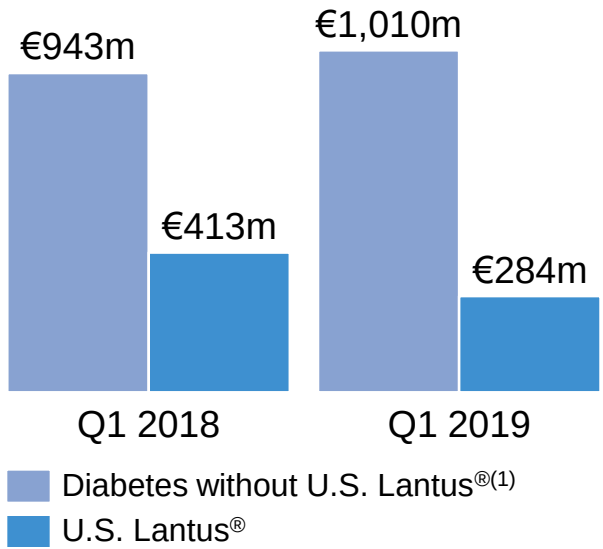

All growth at CER; PPH: Polio / Pertussis (whooping cough) / Haemophilus influenzae type b (Hib)
(1) Meningitis Vaccines

# U.S. pricing dynamics continue to pressure performance of Primary Care core brands

- Primary Care sales €3,935m, down 4.7%
- Diabetes sales €1,294m down 6.9%
  - U.S. sales down -23% to €445m; U.S. Lantus® sales -37%
  - Non-U.S. sales +3.5%, driven by Emerging Markets +15.3%
- Praluent®(2) sales up 10% to €56m
  - U.S. sales €20m, -27%, reflecting significantly increased rebates
  - EMA approval and U.S. FDA potential approval to reduce the risk of CV events(3)
- Established Rx Products sales €2,506m, down 3.8%
  - EU Generics divestment in Q3 2018 led to -9.3% decline at CER

## Global Diabetes Sales

*(in € million)*




All growth at Constant Exchange Rates (CER) and constant structure (CS) adjusting for the EU generics disposal, unless otherwise specified

(1) Includes Adlyxin®, Admelog®, Amaryl®, Apidra®, Insuman®, Soliqua®, Toujeo® and others

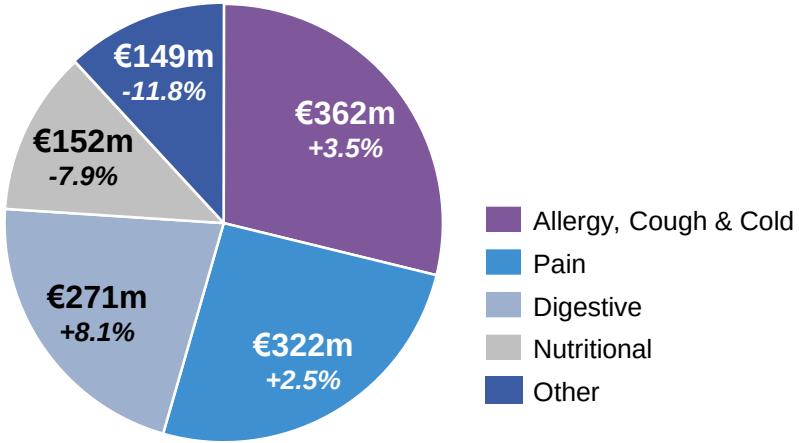
(2) In collaboration with Regeneron

(3) Based on ODYSSEY Outcomes

# CHC performance supported by growth across key categories in emerging markets in Q1

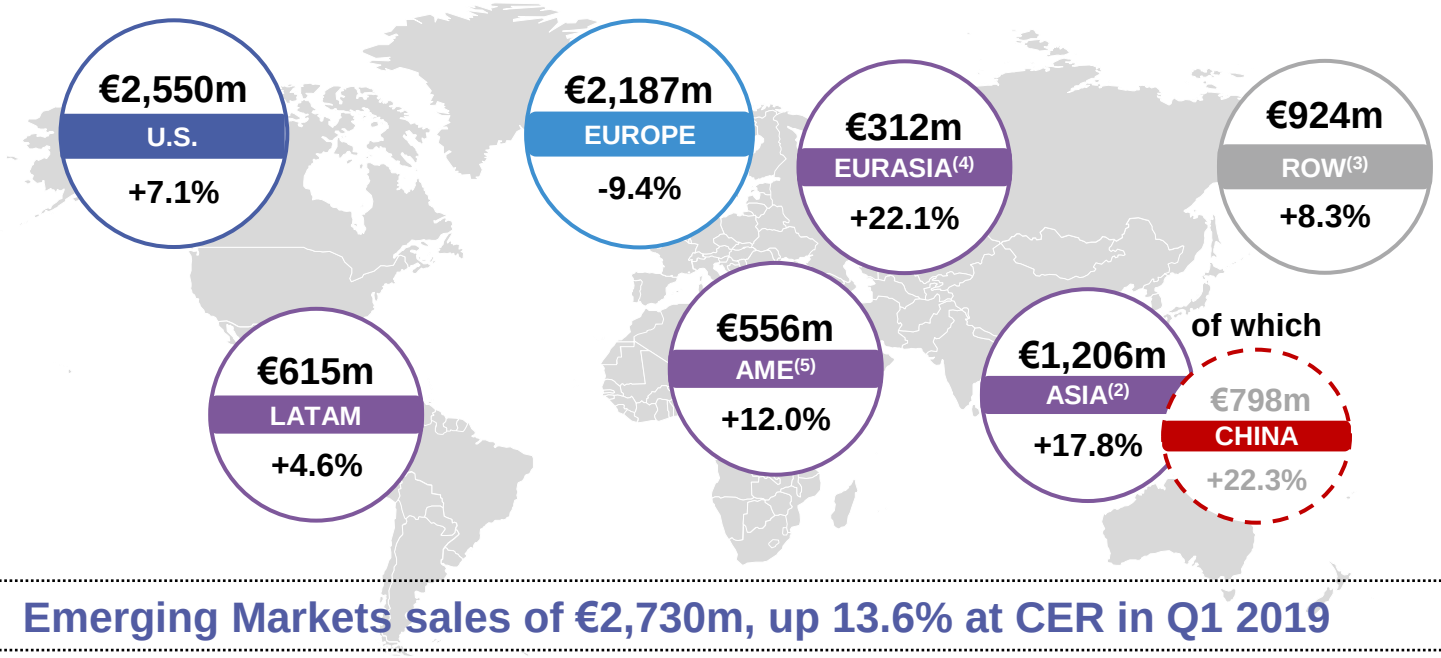
- CHC sales increased 0.6% to €1,256m
- Growth in Allergy, Cough & Cold, Pain, and Digestive
  - Strong sales in Emerging Markets (+8.1%) driven by Latin America region, improved performance in Russia and China
  - Slow start to the U.S. allergy season and weak cough and cold season in Europe decreased sales in mature markets
- Divestments of non-strategic brands
  - Sales impacted by disposals in Europe and Canada

## Q1 2019 CHC sales by categories



# Double-digit growth in Emerging Markets(1) driven primarily by high contribution from China in Q1 2019

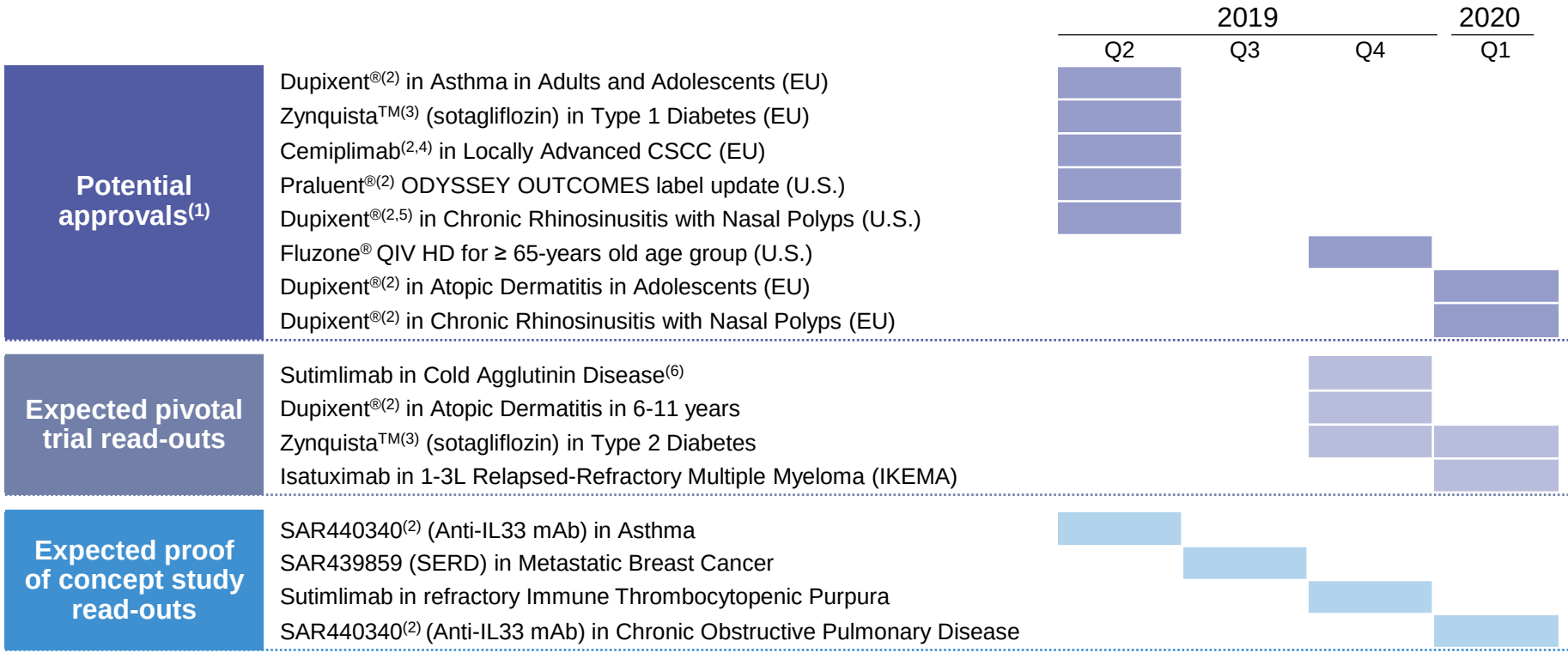
## Geographic breakdown of Q1 2019 sales




**Emerging Markets sales of €2,730m, up 13.6% at CER in Q1 2019**

All growth at CER unless specified otherwise
(1) World excluding U.S., Canada, Europe, Japan, South Korea, Australia, New Zealand, Puerto Rico
(2) Includes China
(3) RoW: Japan, South Korea, Canada, Australia, New Zealand and Puerto Rico
(4) Eurasia: Russia, Ukraine, Georgia, Belarus, Armenia and Turkey
(5) AME: Africa and Middle East

# Several potentially significant approvals for new drugs and additional indications over next 12 months




CSCC: Cutaneous Squamous Cell Carcinoma; SERD: Selective Estrogen Receptor Degrader; QIV: Quadrivalent Influenza Vaccine; HD: High-Dose

(1) Unless specified otherwise, table indicates first potential approval in the U.S. or EU
(2) In collaboration with Regeneron
(3) In collaboration with Lexicon
(4) Also known as SAR439684 and REGN2810
(5) Breakthrough designation granted, priority review granted
(6) Breakthrough designation granted

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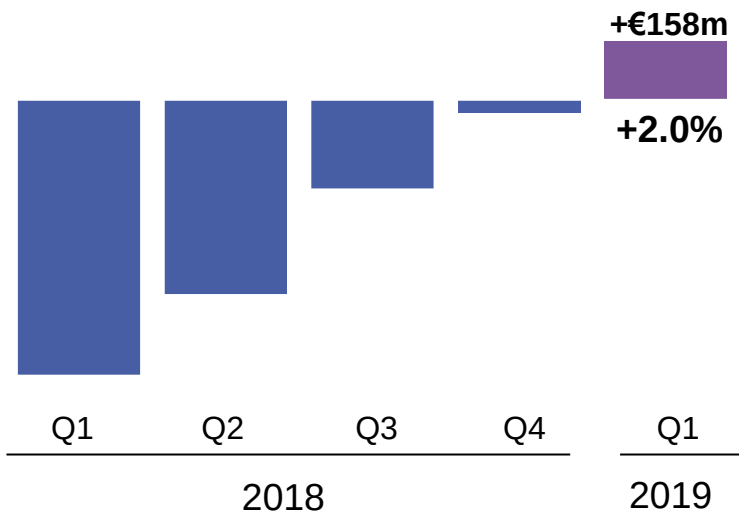
# Financial results

**Jean-Baptiste de Chatillon**
Executive Vice President, Chief Financial Officer

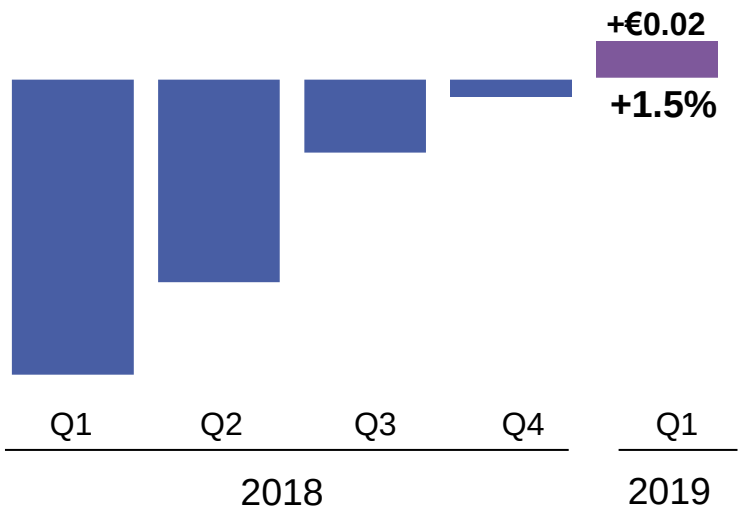
# FX benefit on sales and EPS in Q1 mainly attributable to strengthening U.S. dollar

## Currency impact

### Company sales(1)




### Business EPS




(1) Main currency impact on Company Sales in Q1 2019: US Dollar (+€202m), Brazilian Real (-€19m), Russian Ruble (-€11m), Japanese Yen (+€31m), Argentine Peso (-€55m) and Turkish Lira (-€32m)

# Double-digit BOI growth driven by increased sales, favorable mix and cost containment

| €m | Q1 2019 | Q1 2018 | % Change (CER) |
|---|---|---|---|
| **Net Sales** | **8,391** | **7,898** | **+4.2%** |
| Other revenues | 322 | 228 | +31.6% |
| Gross Profit | 6,097 | 5,611 | +6.3% |
| *Gross margin %* | *72.7%* | *71.0%* | |
| R&D | (1,385) | (1,280) | +4.9% |
| SG&A | (2,380) | (2,310) | +0.6% |
| Other current operating income & expenses | (102) | (31) | - |
| Share of profit/loss from associates | 71 | 74 | - |
| Minority interests | (10) | (30) | - |
| **Business Operating Income** | **2,291** | **2,034** | **+11.3%** |
| *Business operating margin* | *27.3%* | *25.8%* | |

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CER: Constant Exchange Rates

# Strong business EPS growth in Q1 despite higher net financial expenses and broadly flat share count

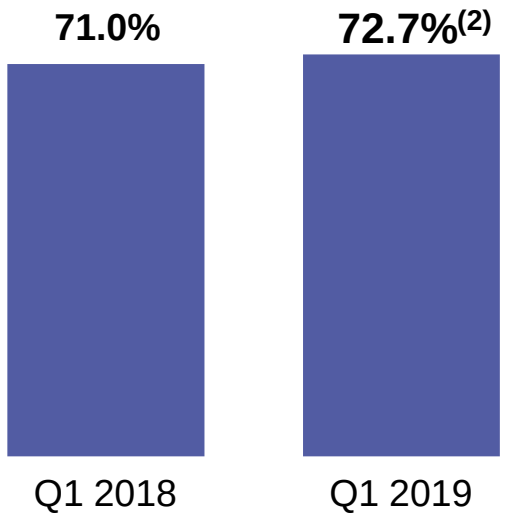
| €m | Q1 2019 | Q1 2018 | % Change (reported €) | % Change (CER) |
|---|---|---|---|---|
| **Net Sales** | **8,391** | **7,898** | **+6.2%** | **+4.2%** |
| Gross Profit | 6,097 | 5,611 | +8.7% | +6.3% |
| *Gross Profit margin %* | *72.7%* | *71.0%* | - | - |
| Business Operating Income | 2,291 | 2,034 | +12.6% | +11.3% |
| *Business operating margin %* | *27.3%* | *25.8%* | - | - |
| *Effective tax rate* | *22.0%* | *22.0%* | - | - |
| Net Financial Income/(Expense) | (45) | 2 | - | - |
| **Total Business Net Income** | **1,765** | **1,598** | **+10.5%** | **+9.0%** |
| Average number of Shares | 1,245.8 | 1,248.2 | - | - |
| **Business EPS** | **€1.42** | **€1.28** | **+10.9%** | **+9.4%** |



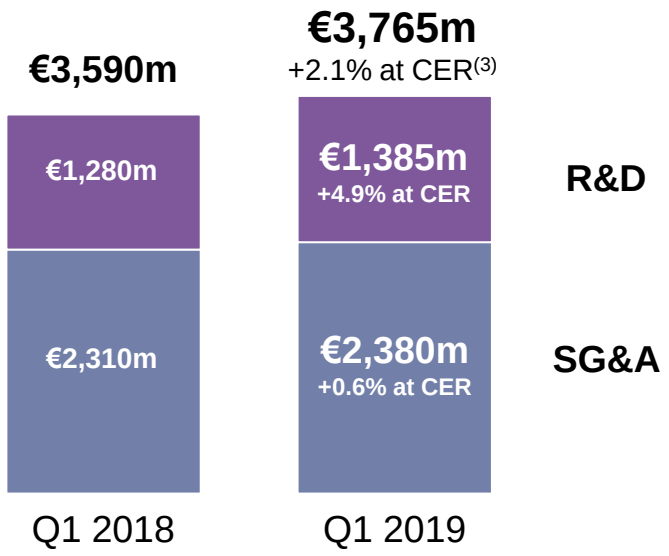
CER: Constant Exchange Rates

# Q1 gross margin benefited from strong China growth and product mix; Opex in-line with expectations

## Gross margin ratio(1)




## Operating expenses




CER: Constant Exchange Rates

(1) Gross Margin is calculated as the ratio of Gross Profit to Company sales (excluding Other revenues)

(2) Gross Margin at CER was 72.4%

(3) Operating Expense growth at CER ex-acquisitions and EU Generics business was +0.7% (SG&A 0.0%; R&D +1.9%)

# Reaffirming FY 2019 financial guidance

| FY 2019 | SANOFI |
|---|---|
| Business EPS | **+3% to +5% at CER(1,2)** |
| FX impact on Business EPS | **Approximately +2%(3)**<br>based on April 2019 average exchange rates |

(1) Compared to FY2018 and barring major unforeseen adverse events
(2) FY 2018 Business EPS was €5.47
(3) Difference between variation on a reported basis and variation at CER

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# Key highlights

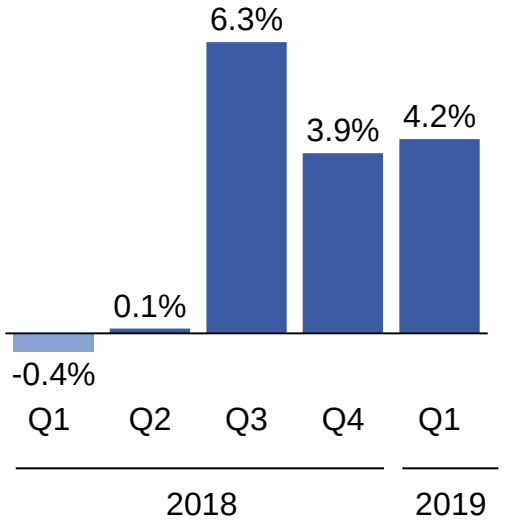
**Olivier Brandicourt**

Chief Executive Officer

# New growth phase continued in Q1 2019

- ✓ Improved growth profile extended into Q1 2019
- ✓ Impressive Dupixent® launch execution
- ✓ U.S. pricing pressures impact Primary Care
- ✓ Strong start with double-digit BOI growth
- ✓ Reaffirming 2019 Full-Year Guidance

## Net sales growth
(at CER)



# Save the Date: Meet Sanofi Management

**Wednesday, June 26, 2019**

Series of in-depth Q&A discussions

Management presentations

**Sanofi Headquarters - Paris**

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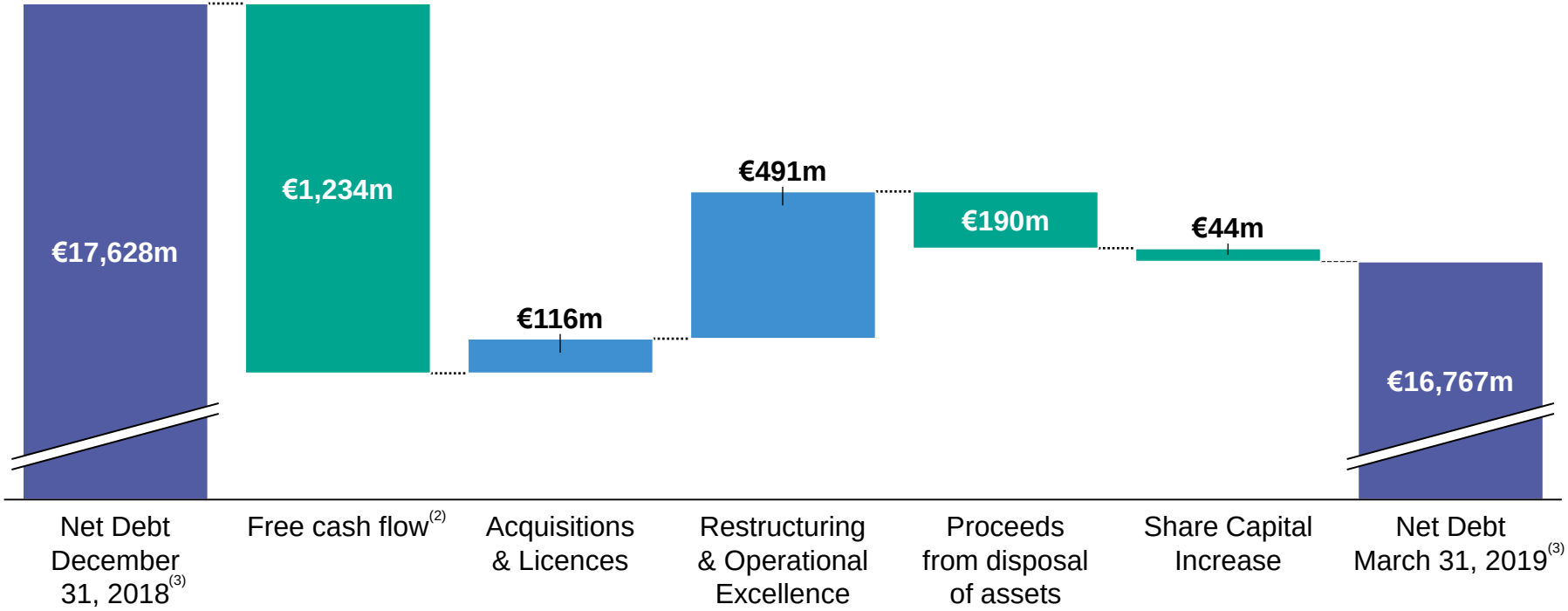
# Finance appendices

# Net debt evolution in Q1 2019(1)



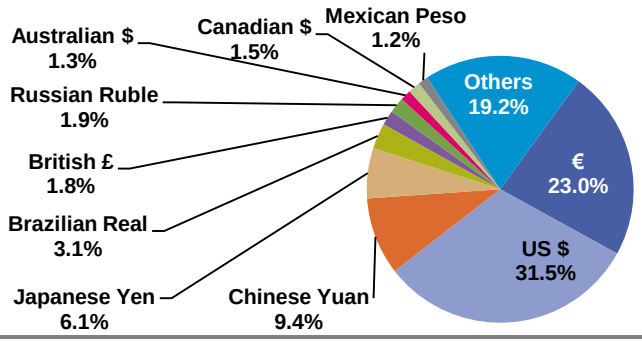

(1) Credit ratings reaffirmed: Moody's A1/stable, S&P AA/stable, Scope AA/stable as of March 31, 2019
(2) Excluding restructuring costs & similar items
(3) Including derivatives related to the financial debt: +€85m at December 31 2018 and +€69m at March 31 2019

# 2019 currency sensitivity and Q1 2019 currency exposure

## 2019 Business EPS Currency Sensitivity

| Currency | Variation | Business EPS Sensitivity |
|---|---|---|
| U.S. Dollar | + 0.05 USD/EUR | - EUR 0.10 |
| Japanese Yen | + 5 JPY/EUR | - EUR 0.02 |
| Chinese Yuan | + 0.2 CNY/EUR | - EUR 0.02 |
| Brazilian Real | + 0.4 BRL/EUR | - EUR 0.01 |
| Russian Ruble | + 10 RUB/EUR | - EUR 0.03 |

## Currency Exposure on Q1 2019 Sales




## Currency Average Rates

| | Q1 2018 | Q1 2019 | *% change* |
|---|---|---|---|
| EUR/USD | 1.23 | 1.14 | *-7.6%* |
| EUR/JPY | 133.16 | 125.12 | *-6.0%* |
| EUR/CNY | 7.81 | 7.67 | *-1.8%* |
| EUR/BRL | 3.99 | 4.28 | *+7.2%* |
| EUR/RUB | 69.93 | 74.91 | *+7.1%* |

# Business Net Income Statement – Q1 2019

| Merci beaucou | Pharmaceuticals | | | Consumer Healthcare | | | Vaccines | | | Others [1] | | | Total Group | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **€ million** | **Q1 2019** | **Q1 2018** | *Change* | **Q1 2019** | **Q1 2018** | *Change* | **Q1 2019** | **Q1 2018** | *Change* | **Q1 2019** | **Q1 2018** | *Change* | **Q1 2019** | **Q1 2018** | *Change* |
| **Net sales** | **6,262** | **5,949** | ***5.3%*** | **1,256** | **1,238** | ***1.5%*** | **873** | **711** | ***22.8%*** | **-** | **-** | **-** | **8,391** | **7,898** | ***6.2%*** |
| Other revenues | 80 | 58 | *37.9%* | - | - | - | 242 | 170 | *42.4%* | - | - | - | 322 | 228 | *41.2%* |
| Cost of Sales | (1,581) | (1,587) | *(0.4%)* | (396) | (399) | *(0.8%)* | (572) | (475) | *20.4%* | (67) | (54) | *24.1%* | (2,616) | (2,515) | *4.0%* |
| *As % of net sales* | *(25.2%)* | *(26.7%)* | | *(31.5%)* | *(32.2%)* | | *(65.5%)* | *(66.8%)* | | | | | *(31.2%)* | *(31.8%)* | |
| **Gross Profit** | **4,761** | **4,420** | ***7.7%*** | **860** | **839** | ***2.5%*** | **543** | **406** | ***33.7%*** | **(67)** | **(54)** | ***24.1%*** | **6,097** | **5,611** | ***8.7%*** |
| ***As % of net sales*** | ***76.0%*** | ***74.3%*** | | ***68.5%*** | ***67.8%*** | | ***62.2%*** | ***57.1%*** | | | | | ***72.7%*** | ***71.0%*** | |
| Research and development expenses | (1,073) | (978) | *9.7%* | (35) | (28) | *25.0%* | (133) | (126) | *5.6%* | (144) | (148) | *(2.7%)* | (1,385) | (1,280) | *8.2%* |
| *As % of net sales* | *(17.1%)* | *(16.4%)* | | *(2.8%)* | *(2.3%)* | | *(15.2%)* | *(17.7%)* | | | | | *(16.5%)* | *(16.2%)* | |
| Selling and general expenses | (1,275) | (1,254) | *1.7%* | (394) | (389) | *1.3%* | (173) | (153) | *13.1%* | (538) | (514) | *4.7%* | (2,380) | (2,310) | *3.0%* |
| *As % of net sales* | *(20.4%)* | *(21.1%)* | | *(31.4%)* | *(31.4%)* | | *(19.8%)* | *(21.5%)* | | | | | *(28.4%)* | *(29.2%)* | |
| Other operating income/expenses | (87) | (7) | | 11 | 5 | | - | 2 | | (26) | (31) | | (102) | (31) | |
| Share of profit/loss of associates* and joint-ventures | 71 | 75 | | - | - | | - | (1) | | - | - | | 71 | 74 | |
| Net income attributable to non controlling interests | (6) | (26) | | (4) | (4) | | - | - | | - | - | | (10) | (30) | |
| **Business operating income** | **2,391** | **2,230** | ***7.2%*** | **438** | **423** | ***3.5%*** | **237** | **128** | ***85.2%*** | **(775)** | **(747)** | ***3.7%*** | **2,291** | **2,034** | ***12.6%*** |
| ***As % of net sales*** | ***38.2%*** | ***37.5%*** | | ***34.9%*** | ***34.2%*** | | ***27.1%*** | ***18.0%*** | | | | | ***27.3%*** | ***25.8%*** | |
| Financial income & expenses | | | | | | | | | | | | | (45) | 2 | |
| Income tax expenses | | | | | | | | | | | | | (481) | (438) | |
| *Tax rate*** | | | | | | | | | | | | | *22.0%* | *22.0%* | |
| **Business net income** | | | | | | | | | | | | | **1,765** | **1,598** | ***10.5%*** |
| ***As % of net sales*** | | | | | | | | | | | | | ***21.0%*** | ***20.2%*** | |
| **Business earnings / share (in €)*** ** | | | | | | | | | | | | | **1.42** | **1.28** | ***10.9%*** |

* Net of tax.
** Determined on the basis of Business income before tax, associates, and non-controlling interests.
*** Based on an average number of shares outstanding of 1,245.8 million in the first quarter of 2019 and 1,248.2 million in the first quarter of 2018.
(1) Other includes the cost of global support functions (Medical Affairs, External Affairs, Finance, Human Resources, Information Solution & Technologies, Sanofi Business Services, etc.)

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# Consolidated Income Statements

| € million | Q1 2019 | Q1 2018 |
|---|---|---|
| **Net sales** | **8,391** | **7,898** |
| Other revenues | 322 | 228 |
| Cost of sales | (2,618) | (2,545) |
| **Gross profit** | **6,095** | **5,581** |
| Research and development expenses | (1,385) | (1,280) |
| Selling and general expenses | (2,376) | (2,312) |
| Other operating income | 64 | 25 |
| Other operating expenses | (166) | (56) |
| Amortization of intangible assets | (557) | (458) |
| Impairment of intangible assets | (5) | (3) |
| Fair value remeasurement of contingent consideration | 60 | (56) |
| Restructuring costs and similar items | (321) | (191) |
| Other gains and losses and litigation[(1)] | - | (49) |
| **Operating income** | **1,409** | **1,201** |
| Financial expenses | (106) | (95) |
| Financial income | 52 | 97 |
| **Income before tax and associates and joint ventures** | **1,355** | **1,203** |
| Income tax expense | (255) | (187) |
| Share of profit / loss of associates and joint ventures | 47 | 30 |
| **Net income excluding the held for exchange Animal Health business** | **1,147** | **1,046** |
| Net income from the held for exchange Animal Health Business | - | (1) |
| **Net income** | **1,147** | **1,045** |
| Net income attributable to non-controlling interests | 10 | 29 |
| **Net income attributable to equity holders of Sanofi** | **1,137** | **1,016** |
| Average number of shares outstanding (million) | 1,245.8 | 1,248.2 |
| **Earnings per share excluding the held for exchange Animal Health Business (in euros)** | **0.91** | **0.81** |
| **IFRS Earnings per share (in euros)** | **0.91** | **0.81** |

(1) In 2018, separation costs for the European Generics business divestiture..

# Reconciliation of Business Net Income to consolidated Net income attributable to equity holders of Sanofi – Q1 2019

| € million | Q1 2019 | Q1 2018 | Change |
|---|---|---|---|
| **Net income attributable to equity holders of Sanofi** | **1,137** | **1,016** | ***11.9%*** |
| Amortization of intangible assets[1] | 557 | 458 | |
| Impairment of intangible assets | 5 | 3 | |
| Fair value remeasurement of contingent consideration | (60) | 56 | |
| Expenses arising from the impact of business combinations on inventories | 3 | 30 | |
| Other expenses related to business combinations | - | 2 | |
| Restructuring costs and similar items | 321 | 191 | |
| Other gains and losses, and litigation [2] | - | 49 | |
| Effects of IFRS 16 on Lease accounting [3] | 4 | - | |
| Tax effect of items listed above: | (227) | (185) | |
| *Amortization & impairment of intangible assets* | *(138)* | *(122)* | |
| *Fair value remeasurement of contingent consideration* | *(4)* | *(6)* | |
| *Expenses arising from the impact of business combinations on inventories* | - | *(6)* | |
| *Other expenses related to business combinations* | - | *(1)* | |
| *Restructuring costs and similar items* | *(95)* | *(52)* | |
| *Other tax effects* | *10* | *2* | |
| Other tax items [4] | - | (66) | |
| Share of items listed above attributable to non-controlling interests | - | (1) | |
| Restructuring costs of associates and joint-ventures, and expenses arising from the impact of acquisitions on associates and joint-ventures | 25 | 44 | |
| Animal Health items | - | 1 | |
| **Business net income** | **1,765** | **1,598** | ***10.5%*** |
| **IFRS earnings per share[5] (in euros)** | **0.91** | **0.81** | |

(1) Of which related to amortization expense generated by the remeasurement of intangible assets as part of business combinations: €527 million in the first quarter of 2019 and €425 million in the first quarter of 2018.
(2) In 2018, separation costs for the European Generics business divestiture.
(3) Impact of new lease standard IFRS 16, is effective January 1, 2019 using the modified retrospective transition method (no restatement of prior periods), since Business Net Income remains reported as previously under IAS 17 and related interpretations for comparison purposes.
(4) In 2018, mainly due to US tax reform.
(5) Based on an average number of shares outstanding of 1,245.8 million in the first quarter of 2019 and 1,248.2 million in the first quarter of 2018.

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# Research & Development appendices

# R&D Pipeline – New Molecular Entities(*)

## Phase 1
(Total : 17)

**SAR441344**(**)(1)
Anti-CD40L mAb
Multiple Sclerosis

**SAR408701**
Maytansin-loaded anti-CEACAM5 mAb, Solid Tumors

**SAR439459**
anti-TGFb mAb
Advanced Solid Tumors

O **REGN5458**(**)(2)
Anti-BCMA-CD3 bispecific mAb
Relapsing Refractory MM

O **REGN4018**(**)(2)
Anti-MUC16-CD3 bispecific mAb
Ovarian Cancer

**SAR439859**
SERD
Metastatic Breast Cancer

**SAR442720**(**)(3)
SHP2 inhibitor
Solid Tumors

**SAR440234**
T cell engaging multi spe mAb
Leukemia

**SAR441000**(**)(4)
Cytokine mRNA
Solid tumor

**BIVV001**(**)(5)
rFVIIIFc – vWF – XTEN(6)
Hemophilia A

**ST400**(**)(7)
Ex Vivo ZFN Gene-Edited Cell Therapy, Beta thalassemia

**BIVV003**(**)(7)
Ex Vivo ZFN Gene-Edited Cell Therapy, Sickle Cell Disease

**SAR443060**(**)(8)
RIPK1 inh(9)
Amyotrophic Lateral Sclerosis

**Next Gen PCV**(**)(10)
Pneumococcal Conjugate Vaccines

**Herpes Simplex Virus Type 2**
HSV-2 therapeutic vaccine

**Respiratory syncytial virus**
Infants 4-month and older
Vaccines

**SAR441169**(**)(11)
RORC (ROR gamma T) antagonist,
Psoriasis

## Phase 2
(Total : 8)

**SAR440340**(**)(12)
Anti-IL33 mAb
Atopic Dermatitis

**SAR156597**
IL4/IL13 bispecific mAb
Systemic Scleroderma

R **olipudase alfa**
rhASM
AS Deficiency(13)

**SAR339375**
miRNA-21
Alport Syndrome

**SAR422459**(**)(14)
ABCA4 gene therapy
Stargardt Disease

**SAR442168**(**)(15)
BTK inhibitor
Multiple Sclerosis

**HIV**
Viral vector prime & rgp120 boost vaccine

**SP0232**(**)(16)
Respiratory syncytial virus
Monoclonal Antibody

## Phase 3
(Total : 7)

**isatuximab**
Anti-CD38 mAb
3L RRMM (ICARIA)

**avalglucosidase alfa**
Neo GAA
Pompe Disease

**venglustat**
Oral GCS inhibitor
ADPKD(17)

**fitusiran**
RNAi targeting anti-thrombin
Hemophilia A and B

**sutimlimab**(18)
Anti Complement C1s mAb
Cold Agglutinin Disease

**SAR341402**
Rapid acting insulin
Type 1/2 Diabetes

**efpeglenatide**(**)(19)
Long-acting GLP-1 agonist
Type 2 Diabetes

## Registration
(Total : 2)

**cemiplimab**(**)(12)
PD-1 inhibitor mAb
Advanced CSCC (EU)

**Zynquista**TM(**)(20)
Oral SGLT-1&2 inhibitor
Type 1 Diabetes (U.S./EU)

R Registrational Study (other than Phase 3)

O Opt-in rights products for which rights have not been exercised yet

- Immuno-inflammation
- Oncology
- Rare Diseases
- Rare Blood Disorders
- MS & Neuro
- Diabetes
- Cardiovascular & metabolism
- Vaccines

(1) Developed in collaboration with Immunext
(2) Regeneron product for which Sanofi has opt-in rights
(3) Developed in collaboration with REVOLUTION Medicines
(4) Developed in collaboration with BioNtech
(5) Sanofi product for which Sobi has opt-in rights in SOBI territories
(6) Recombinant Coagulation Factor VIII Fc – von Willebrand Factor – XTEN Fusion protein
(7) Developed in collaboration with Sangamo
(8) Developed in collaboration with Denali
(9) Receptor-interacting serine/threonine-protein kinase 1
(10) Developed in collaboration with SK
(11) Developed in collaboration with Lead Pharma
(12) Developed in collaboration with Regeneron
(13) Acid Sphingomyelinase Deficiency also known as Niemann Pick type B
(14) Identification of out-licensing partner ongoing
(15) Developed in collaboration with Principia
(16) Developed in collaboration with AstraZeneca
(17) Autosomal Dominant Polycystic Kidney Disease
(18) Also Known as BIVV009
(19) Developed in collaboration with Hanmi
(20) Developed in collaboration with Lexicon
(*) Phase of projects determined by clinicaltrials.gov disclosure timing
(**) Partnered and/or in collaboration – Sanofi may have limited or shared rights on some of these products

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# Additional Indications(*)

| Phase 1 (Total : 5) | Phase 2 (Total : 19) | | Phase 3 (Total : 21) | | Registration (Total : 5) |
|---|---|---|---|---|---|
| **SAR439459 + cemiplimab(**)(1)**<br>Anti-TGFb mAb + PD-1 inh mAb<br>Advanced Solid Tumors | **dupilumab(**)(1)**<br>Anti-IL4Rα mAb<br>Grass Immunotherapy | **isatuximab + cemiplimab(**)(1)**<br>Anti-CD38 mAb + PD-1 inh mAb<br>Relapsing Refractory MM | **dupilumab(**)(1)**<br>Anti-IL4Rα mAb<br>Asthma 6 - 11 years old | **Isatuximab**<br>Anti-CD38 mAb<br>Newly Diag. MM Te(9) (GMMG) | **dupilumab(**)(1)**<br>Anti-IL4Rα mAb<br>Asthma 12y+ (EU) |
| O **cemiplimab(**)(1) + REGN4018(2)**<br>PD-1 inh mAb + Anti-MUC16-CD3 bispe mAb - Ovarian Cancer | R **sarilumab(**)(1)**<br>Anti-IL6R mAb<br>Polyarticular JIA(6) | **isatuximab + cemiplimab(**)(1)**<br>Anti-CD38 mAb + PD-1 inh mAb<br>Advanced Malignancies | **dupilumab(**)(1)**<br>Anti-IL4Rα mAb<br>Eosinophilic Esophagitis | **isatuximab**<br>Anti-CD38 mAb<br>1-3L RRMM (IKEMA) | **Dupixent®(**)(1)**<br>dupilumab<br>AD 12 – 17 years old (EU) |
| **SAR439859 + palbociclib**<br>SERD + CDK4/6 inh<br>Metastatic Breast Cancer | **sarilumab(**)(1)**<br>Anti-IL6R mAb<br>Systemic Juvenile Arthritis | **isatuximab + cemiplimab(**)(1)**<br>Anti-CD38 mAb + PD-1 inh mAb<br>Lymphoma | **Dupixent®(**)(1)**<br>dupilumab<br>AD 6 – 11 years old | **Aubagio®**<br>teriflunomide<br>RMS – Pediatric | **dupilumab(**)(1)**<br>Anti-IL4Rα mAb<br>CRSwNP |
| **sutimlimab(3)**<br>Anti Complement C1s mAb<br>Immune Thrombocytopenic Purpura | **SAR440340(**)(1)**<br>Anti-IL33 mAb<br>COPD | **isatuximab + atezolizumab(7)**<br>Anti-CD38 mAb + PD-L1 inh mAb<br>mCRC | **Dupixent®(**)(1)**<br>dupilumab<br>AD 6 months - 5 years old | **Lemtrada®**<br>alemtuzumab<br>RRMS - Pediatric | **Praluent®(**)(1)**<br>alirocumab<br>CV events reduction (U.S.) |
| **SAR443060(4)**<br>RIPK1 inh(5)<br>Alzheimer's Disease | **dupilumab(**)(1) + AR101**<br>Anti-IL4Rα mAb + Immunotherapy<br>Peanut Allergy - Pediatric | **isatuximab + atezolizumab(7)**<br>Anti-CD38 mAb + PD-L1 inhibitor mAb<br>Solid Tumors | **sarilumab(**)(1)**<br>Anti-IL6R mAb<br>Giant Cell Arteritis | **Zynquista™(**)(10)**<br>Oral SGLT-1&2 inh.<br>Worsening Heart Failure in Diabetes | **Fluzone® QIV HD**<br>Quadrivalent inactivated<br>Influenza vaccine - High dose |
| | **SAR440340(**)(1)**<br>Anti-IL33 mAb<br>Asthma | **Venglustat**<br>Oral GCS inhibitor<br>Fabry Disease | **sarilumab(**)(1)**<br>Anti-IL6R mAb<br>Polymyalgia Rheumatica | **Zynquista™(**)(10)**<br>Oral SGLT-1&2 inhibitor<br>Type 2 Diabetes | |
| | **dupilumab(**)(1)**<br>Anti-IL4Rα mAb<br>COPD | **Venglustat**<br>Oral GCS inhibitor<br>Gaucher Type 3 | **cemiplimab(**)(1)**<br>PD-1 inh mAb<br>1L NSCLC | **Cerdelga®**<br>Eliglustat<br>Gaucher T1, ERT switch Pediatric | |
| | R **cemiplimab(**)(1)**<br>PD-1 inhibitor mAb<br>Advanced Basal Cell Carcinoma | **Venglustat**<br>Oral GCS inhibitor<br>Gaucher related Parkinson's Dis. | **cemiplimab(**)(1)+ chemotherapy**<br>PD-1 inh mAb + chemotherapy<br>1L NSCLC | **Praluent® (**)(1)**<br>Alirocumab<br>LDL-C reduction - Pediatric | |
| | **Isatuximab**<br>Anti-CD38 mAb<br>1-2L AML / ALL pediatrics | **VerorabVax® (VRVg)**<br>Purified vero rabies vaccine | **cemiplimab(**)(1)**<br>PD-1 inhibitor mAb<br>2L Cervical Cancer | **Men Quad TT**<br>Advanced generation meningococcal ACYW conjugate vaccine | |
| | | **SP0173**<br>Tdap booster US | **Isatuximab**<br>Anti-CD38 mAb<br>1L Newly Diag. MM Ti(8) (IMROZ) | **Pediatric pentavalent vaccine**<br>DTP-Polio-Hib<br>Japan | |
| | | | | **Shan 6**<br>DTP-HepB-Polio-Hib<br>Pediatric hexavalent vaccine | |

R Registrational study (other than Phase 3)

O Opt-in rights products for which rights have not been exercised yet

(1) Developed in collaboration with Regeneron
(2) Regeneron product for which Sanofi has opt-in rights
(3) Also known as BIVV009
(4) Developed with Denali
(5) Receptor-interacting serine/threonine-protein kinase 1
(6) JIA: Juvenile Idiopathic Arthritis
(7) Studies in collaboration with Roche (atezolizumab)
(8) Transplant ineligible
(9) Transplant eligible
(10) Developed in collaboration with Lexicon
(*) Phase of projects determined by clinicaltrials.gov disclosure timing
(**) Partnered and/or in collaboration - Sanofi may have limited or shared rights on some of these products

- Immuno-inflammation
- Oncology
- Rare Diseases
- Rare Blood Disorders
- MS & Neuro
- Diabetes
- Cardiovascular & metabolism
- Vaccines

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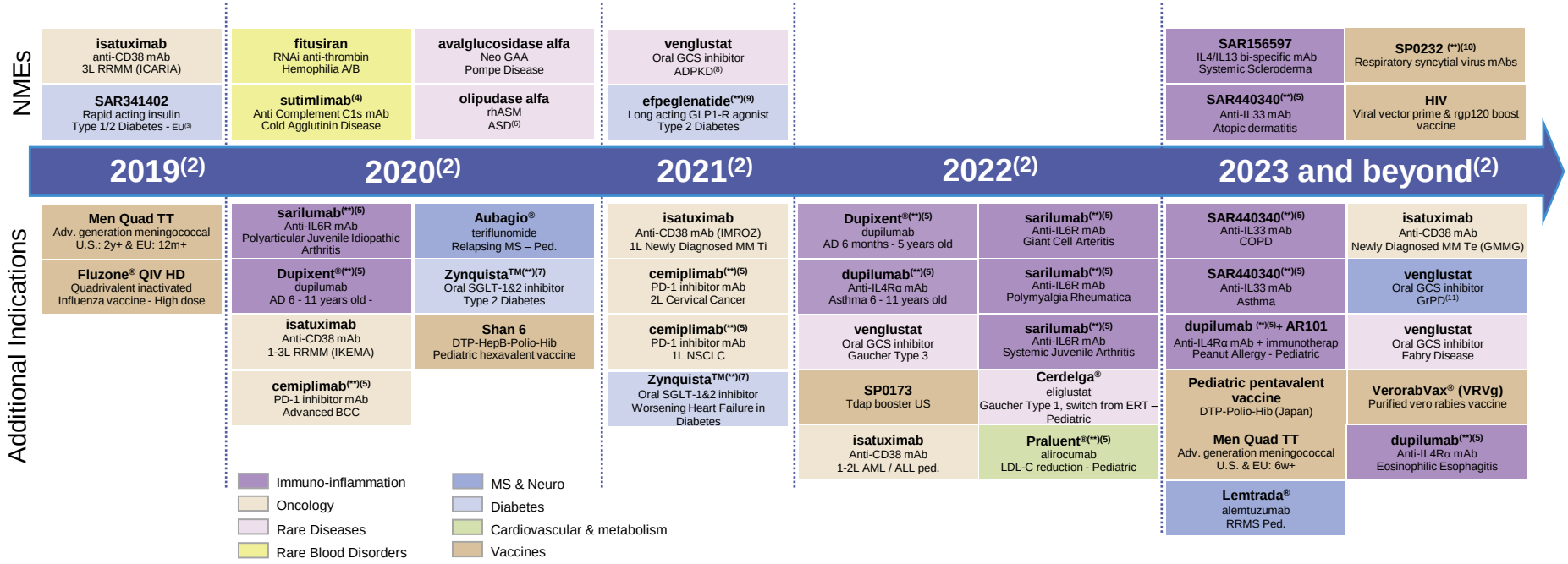
# Expected Submission Timeline(1)




(1) Excluding Phase 1
(2) Projects within a specified year are not arranged by submission timing
(3) Submission strategy for the U.S. under evaluation
(4) Also known as BIVV009
(5) Developed in collaboration with Regeneron
(6) Acid Sphingomyelinase Deficiency
(7) Developed in collaboration with Lexicon
(8) Autosomal Dominant Polycystic Kidney Disease
(9) Developed in collaboration with Hanmi
(10) Developed in collaboration with AstraZeneca
(11) Gaucher related Parkinson's Disease
(**) Partnered and/or in collaboration – Sanofi may have limited or shared rights on some of these products

# Pipeline Movements Since Q4 2018

| | Additions | Removals |
|---|---|---|
| Registration | **dupilumab**(**)(1) Anti-IL4Rα mAb CRSwNP<br>**Fluzone® QIV HD** Quadrivalent inactivated Influenza vaccine - High dose) | |
| Phase 3 | | |
| Phase 2 | **isatuximab** Anti-CD38 mAb 1-2L AML / ALL pediatrics<br>**dupilumab**(**)(1) Anti-IL4Rα mAb COPD<br>**SAR442168**(**)(2) BTK inhibitor Multiple Sclerosis | |
| Phase 1 | **SAR441169** (**)(3) RORC (ROR gamma T) antagonist Psoriasis | |

(1) Developed in collaboration with Regeneron
(2) Developed in collaboration with Principia
(3) Developed in collaboration with Lead Pharma
(**) Partnered and/or in collaboration – Sanofi may have limited or shared rights on some of these products

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# R&D Pipeline Summary – Total Projects[(1)]

| | Phase 1 | Phase 2 | Phase 3 | Registration | TOTAL |
|---|---|---|---|---|---|
| Immuno-inflammation | 1 | 9 | 6 | 3 | 19 |
| Oncology | 11 | 7 | 7 | 1 | 26 |
| Rare Diseases | 0 | 4 | 3 | 0 | 7 |
| Rare Blood Disorders | 4 | 0 | 2 | 0 | 6 |
| Multiple Sclerosis and Neurology | 3 | 3 | 2 | 0 | 8 |
| Diabetes | 0 | 0 | 4 | 1 | 5 |
| Cardiovascular Disease | 0 | 0 | 1 | 1 | 2 |
| Vaccines | 3 | 4 | 3 | 1 | 11 |
| TOTAL | **22** | **27** | **28** | **7** | |

**49** **35**

**84** **Total Projects**

(1) Includes 3 Phase 1 products for which Sanofi has Opt-in rights but has not yet exercised these rights

# Expected R&D Milestones

| Products | Expected milestones | Timing |
|---|---|---|
| Dupixent® | EU regulatory decision in Asthma in Adult and Adolescent patients | **Q2 2019** |
| Zynquista™ (sotagliflozin) | EU.regulatory decision in Type 1 Diabetes | **Q2 2019** |
| cemiplimab | EU regulatory decision in Locally Advanced Cutaneous Squamous Cell Carcinoma | **Q2 2019** |
| Praluent® | U.S. regulatory decision in CV events reduction ODYSSEY OUTCOMES | **Q2 2019** |
| Dupixent® | U.S. regulatory decision in Chronic Rhinosinusitis with Nasal Polyps | **Q2 2019** |
| SAR440340 (Anti-IL33 mAb) | Proof of concept study read-out in asthma | **Q2 2019** |
| SAR439859 (SERD) | Proof of concept study read-out in metastatic Breast Cancer | **Q3 2019** |
| sutimlimab | Proof of concept study read-out in refractory Immune Thrombocytopenic Purpura | **Q4 2019** |
| Fluzone® QIV HD | U.S. regulatory decision for ≥ 65-year old age group | **Q4 2019** |
| sutimlimab | Pivotal trial read-out in Cold Agglutinin Disease | **Q4 2019** |
| Dupixent® | Pivotal trial read-out in Atopic Dermatitis in 6-11 years | **Q4 2019** |
| Zynquista™ (sotagliflozin) | Expected pivotal trial read-out in Type 2 Diabetes | **Q4 2019 – Q1 2020** |
| Dupixent® | EU regulatory decision in Atopic Dermatitis in Adolescent patients | **Q1 2020** |
| Dupixent® | EU regulatory decision in Chronic Rhinosinusitis with Nasal Polyps | **Q1 2020** |
| isatuximab | Pivotal trial read-out in 1-3L RRMM (IKEMA) | **Q1 2020** |
| SAR440340 (Anti-IL33 mAb) | Proof of concept study read-out in Chronic Obstructive Pulmonary Disease | **Q1 2020** |