Nirsevimab

Aiming for RSV prophylaxis for all infants

July 30, 2020

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Forward looking statements

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Agenda

Introduction	**Thomas Triomphe**	Global Head of Sanofi Pasteur	
RSV - A major public health burden	**Su-Peing Ng**	Global Head of Medical, Sanofi Pasteur	
Phase 2b data	**Jon Heinrichs**	Global Project Head, nirsevimab, Sanofi Pasteur	
Conclusion	**John Shiver**	Global Head of R&D, Sanofi Pasteur	
Q&A session *(also joining)*	**Paul Hudson**	Chief Executive Officer	
	John Reed	Global Head of R&D	
	Jean-Baptiste de Chatillon	Chief Financial Officer	

Introduction

Thomas Triomphe

Global Head of Sanofi Pasteur

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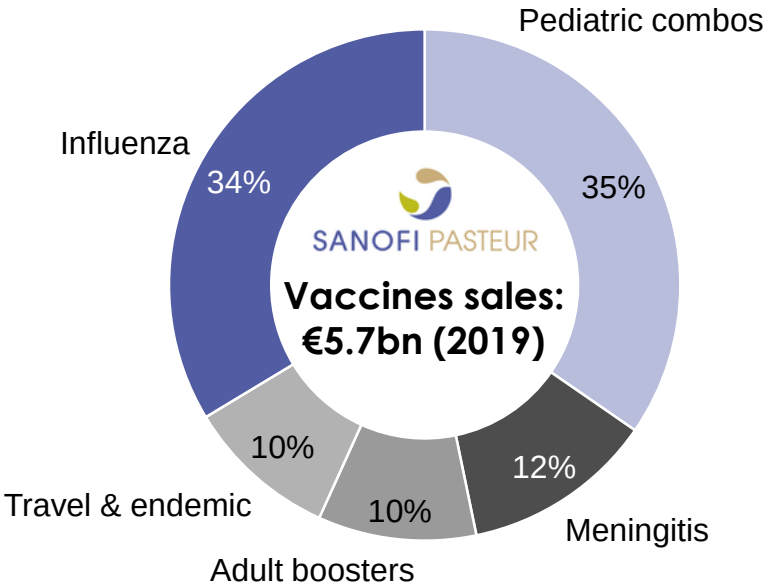
Sanofi – a market leader in both pediatric combos and influenza vaccines

Pediatric combos & influenza account for ~70% of Sanofi vaccines sales



Unique blend of experience to drive success of RSV immunization

- **Pediatric combos** provide insights into the operating model of pediatric medicine
- **Influenza** provides significant experience in launching and supporting seasonal immunization
- Strong knowledge in **respiratory vaccines**
- Track record of **building leading, $1bn+ franchises** in both pediatric & seasonal vaccines

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Source: Sanofi

RSV - A major public health burden

Su-Peing Ng

Global Head of Medical, Sanofi Pasteur

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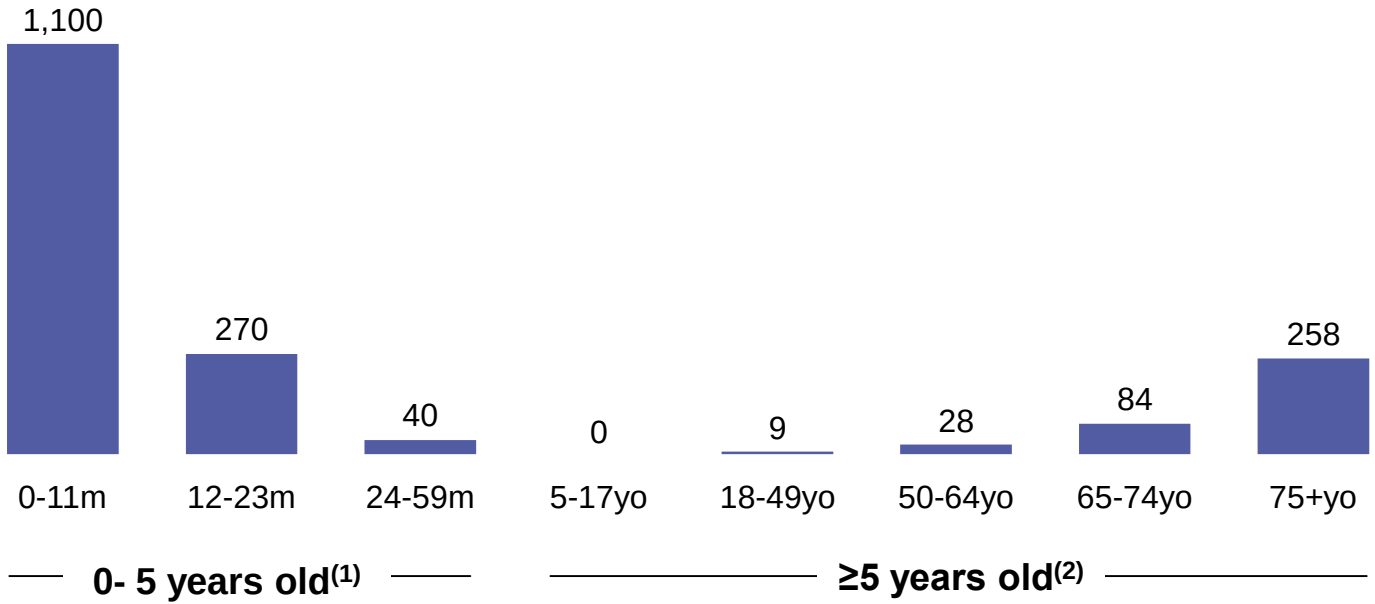
Disease burden greatest for all infants facing their first RSV season

Annual RSV hospitalization rates for all age groups

(U.S., per 100,000)



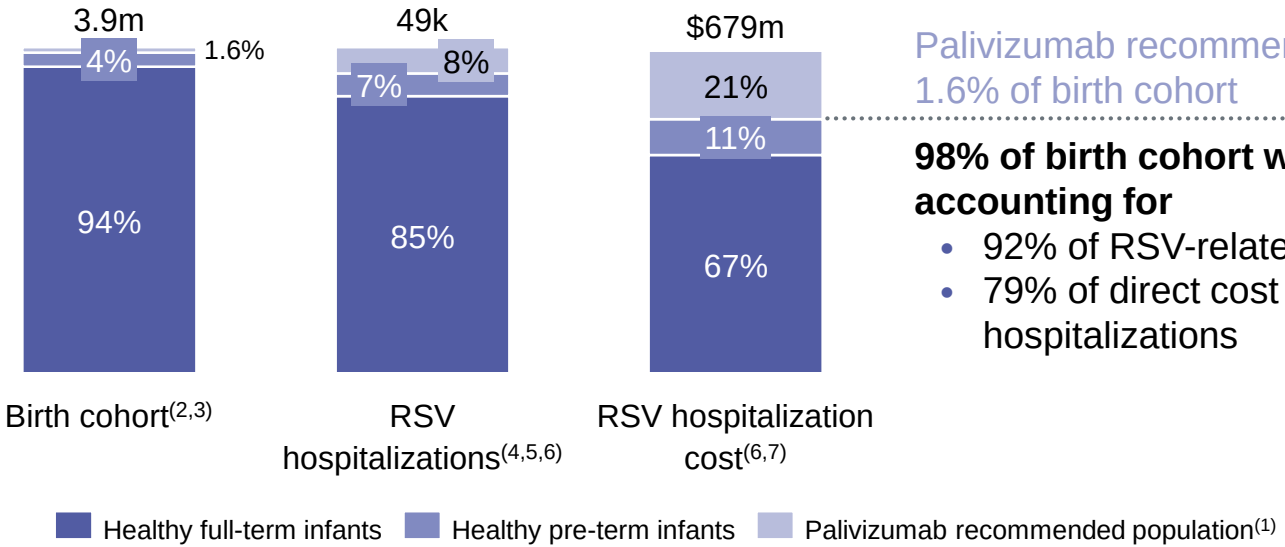
m: months; yo: years old

(1) Hall et al., NEJM, 2009 (averages of 4 RSV seasons 2000-2004) (2) Matias et al.;BMC Public Health (1997-2009 period)

Disease burden – all infants are at risk

Breakdown of U.S. birth cohort, annual RSV hospitalizations and annual hospitalization cost by gestational age

Scope: all infants facing their first RSV season



Palivizumab recommended U.S. population: 1.6% of birth cohort

98% of birth cohort without protection, accounting for

- 92% of RSV-related infant hospitalizations
- 79% of direct cost of RSV-related infant hospitalizations

(1) Palivizumab recommended U.S. population: infants born < 29 wGA and CHD/CLD (2) Pavilack et al. Infect Dis Ther 2018 (3) Chawanpaiboon et al. Lancet Global Health 2019 (4) Feltes, T.F., et al. J Pediatr, 2003 (5) IMpact, The IMpact-RSV Study Group. Pediatrics, 1998 (6) McLaurin et al. J of Perinat 2016 (7) Doucette et al. Plos One 2016
CHD: congenital heart disease; CLD: chronic lung disease; wGA: weeks gestational age
Sanofi internal estimates based on the above sources

Hospitalizations only the tip of the iceberg

RSV cost in the U.S.

Scope: all infants facing their 1st RSV season

	Number of visits	Share of RSV cost Total ~ $2bn
Medical care		
Hospitalizations	49k	~40%
Emergency room visits	129k	~20%
Primary care visits	351k	~10%
Additional costs		
Synagis®	-	~10%
Indirect costs(1)	-	~20%

RSV disease burden beyond costs

- **~215 deaths annually** in the U.S.(2)
- **Burden for healthcare system:** increased capacity needed in pediatrics during winter
- **Burden for families:** emotional toll due to lack of intervention in mild cases and hospitalization in severe ones

(1) Cost of parents' lost income + lifetime income lost by an infant who died of RSV
(2) Scope: all infants facing their first RSV season, Arriola et al. J Pediatric Infect Dis Soc. 2019
Around 4m babies born in the U.S. annually, 24 million in developed markets, see epidemiology deck in appendix
Source: Sanofi internal estimates

Value proposition - prophylaxis for all infants

	Nirsevimab target profile	Palivizumab
Recommended population	**Universal**, targeting all infants regardless of wGA or month of birth	**<2% of birth cohort**, infants born < 29 wGA(1) and CHD/CLD
Efficacy	**>70% relative risk reduction** of RSV related hospitalizations(2)	45-55% relative risk reduction of RSV related hospitalizations(3)
Treatment burden	**One single injection** for the entire first season	Up to 5 monthly doses during RSV season
Market Access	**A cost-effective** all infant strategy **Priced in line with other premium priced pediatric vaccines**	List price of ~$7k for 5 injections excl. healthcare provider cost(4)

(1) Depending on local recommendation (2) Observed efficacy in Phase 2b in pre-terms infants (29-35wGA): 78% relative risk reduction of RSV related hospitalizations
(3) Palivizumab prescribing information – range between Trial 1 and Trial 2 (4) Based on AstraZeneca sales data 2018
CHD: congenital heart disease; CLD: chronic lung disease; wGA: weeks gestational age
Note: no head to head studies have been conducted comparing the investigational treatment nirsevimab with any other therapies. The information listed on this slide involves different study designs, patient populations, and endpoints, and cross trial comparisons of the endpoints should not be made
Note: nirsevimab under investigation in collaboration with AstraZeneca, not approved by regulators

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Phase 2b data

Jon Heinrichs

Global Project Head, nirsevimab,
Sanofi Pasteur

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Half-life extension allows population approach to protect all infants

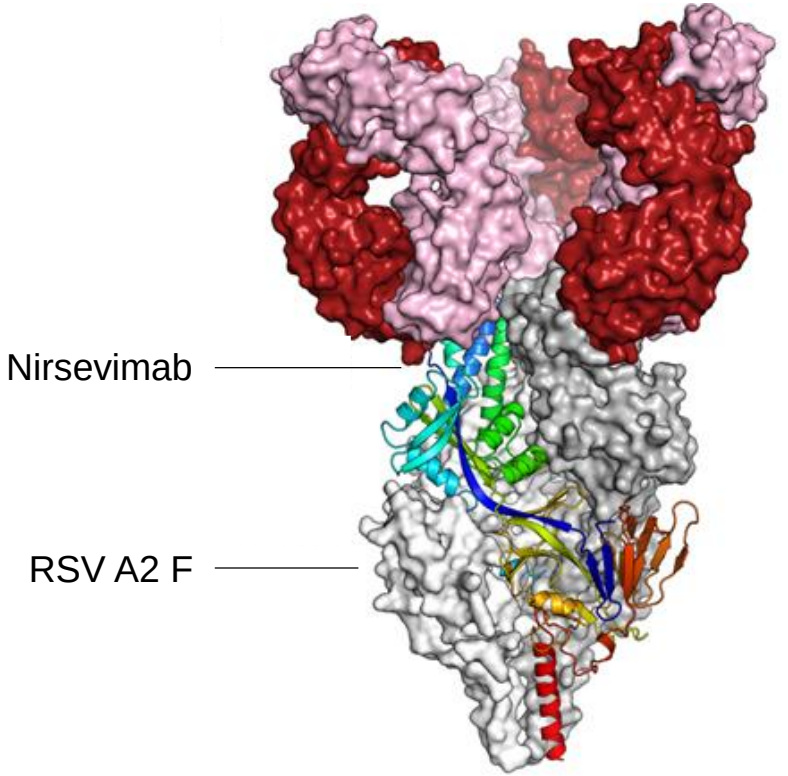
Technology

- Derived from human B-cells
- Potent IgG1 neutralizing mAb
- Targets a conserved epitope on the F protein
- Half-life extension technology

Target profile for all infant strategy

- Immediate protection
- Once per season dosing
- Intramuscular route

FDA Break Through Designation and EMA Priority Medicine



mAb: Monoclonal antibody; Note: nirsevimab under investigation in collaboration with AstraZeneca, not approved by regulators

Phase 2b trial in ~1,500 healthy pre-term infants

Study population

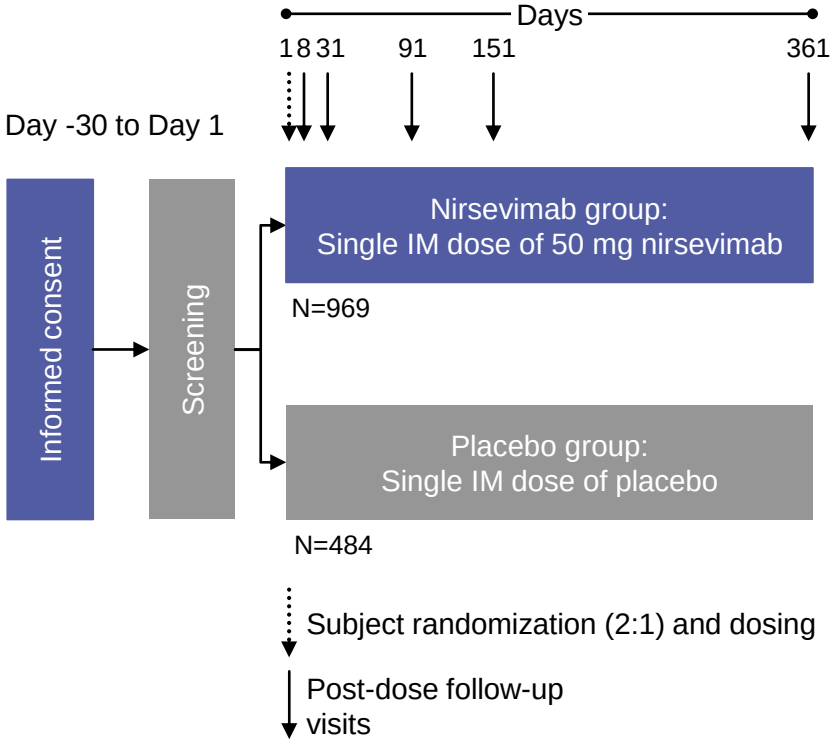
- 1,453 pre-term infants 29-35 wGA

Primary endpoint

- Incidence of medically attended LRTI (in and outpatient) caused by RT-PCR confirmed RSV for 150 days after dosing

Secondary and exploratory endpoints

- Incidence of hospitalization due to RT-PCR-confirmed RSV for 150 days after dosing
- Safety
- Pharmacokinetics
- Health care resource utilization and caregiver burden assessment

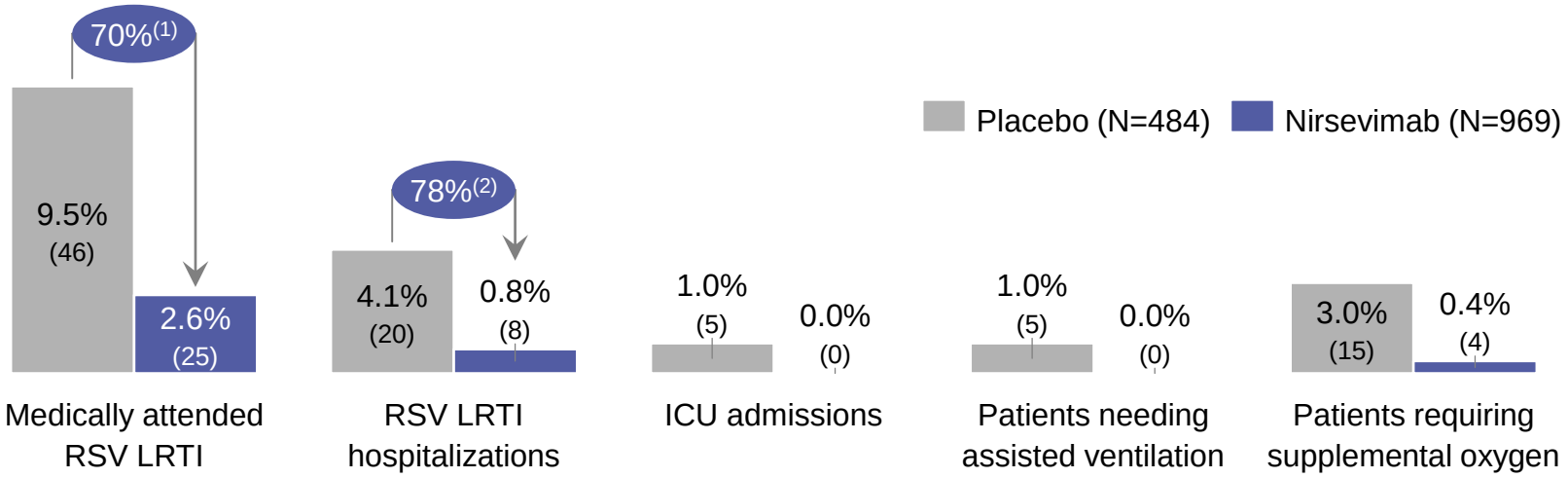


LRTI: Lower respiratory tract infection; wGA: weeks gestational age; RT-PCR: Reverse transcription polymerase chain reaction; IM: Intramuscular
Note: Nirsevimab under investigation in collaboration with AstraZeneca, not approved by regulators
Source: Nirsevimab Phase 2b results, Griffin et al n engl j med 383;5 July 30, 2020

70% reduction of medically attended RSV LRTI

Incidence, in %

(# of cases)



Primary & secondary endpoints
(Poisson regression)

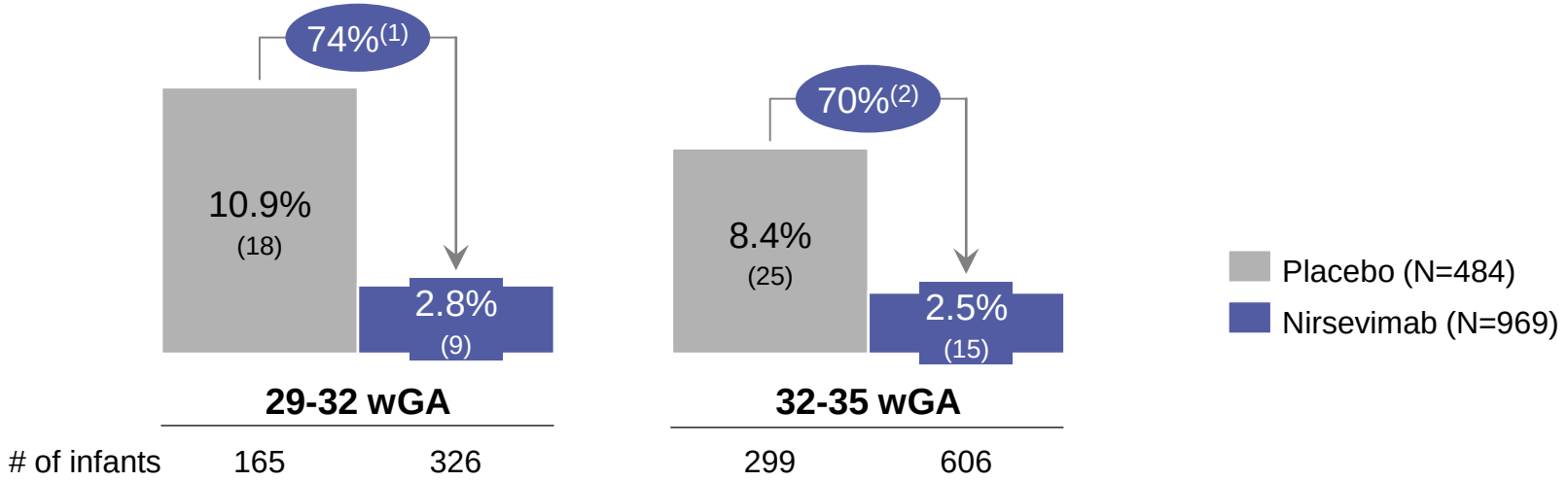
Other RSV-related complications

LRTI: Lower Respiratory Track Infections; ICU: Intensive Care Unit
(1) Relative Reduction Rate, 95% CI: 52.3%, 81.2% (2) Relative Reduction Rate, 95% CI: 51.9%, 90.3%
Source: Nirsevimab Phase 2b results, Griffin et al n engl j med 383;5 July 30, 2020
Note: Nirsevimab under investigation in collaboration with AstraZeneca, not approved by regulators

Consistent efficacy in Ph2b regardless of gestational age

Medically attended RSV LRTI incidence, in %

(# of cases)



Phase 3 MELODY underway to investigate efficacy in full-term infants

LRTI: Lower Respiratory Track Infections; wGA: weeks gestational age; Ph2b- Phase 2b

(1) Relative Reduction Rate, 95% CI: 44.9%, 88.4% (2) Relative Reduction Rate, 95% CI: 44.7%, 84.2%

Source: Nirsevimab Phase 2b results, Griffin et al n engl j med 383;5 July 30, 2020 Note: Nirsevimab under investigation in collaboration with AstraZeneca, not approved by regulators

Safety results similar to placebo

Parameter, n (%)	Placebo (N=479)	Nirsevimab (N=968)
Treatment emergent adverse events	**416 (86.8)**	**834 (86.2)**
Considered related to study drug	10 (2.1)	22 (2.3)
≥Grade 3 severity	60 (12.5)	77 (8.0)
Occurred ≤1 day post-dose	12 (2.5)	24 (2.5)
Occurred ≤7 days post-dose	73 (15.2)	121 (12.5)
Deaths	**3 (0.6)**	**2 (0.2)**
Treatment emergent serious adverse events	**81 (16.9)**	**108 (11.2)**
Considered related to study drug	0	0
Adverse events of special interest	**3 (0.6)**	**5 (0.5)**
Considered related to study drug	3 (0.6)	5 (0.5)

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Source: Nirsevimab Phase 2b results, Griffin et al n engl j med 383;5 July 30, 2020 Note: Nirsevimab under investigation in collaboration with AstraZeneca, not approved by regulators

Passive immunization - only approach developed to immediately protect all infants for the entire 1st season

mAb immunization (passive):

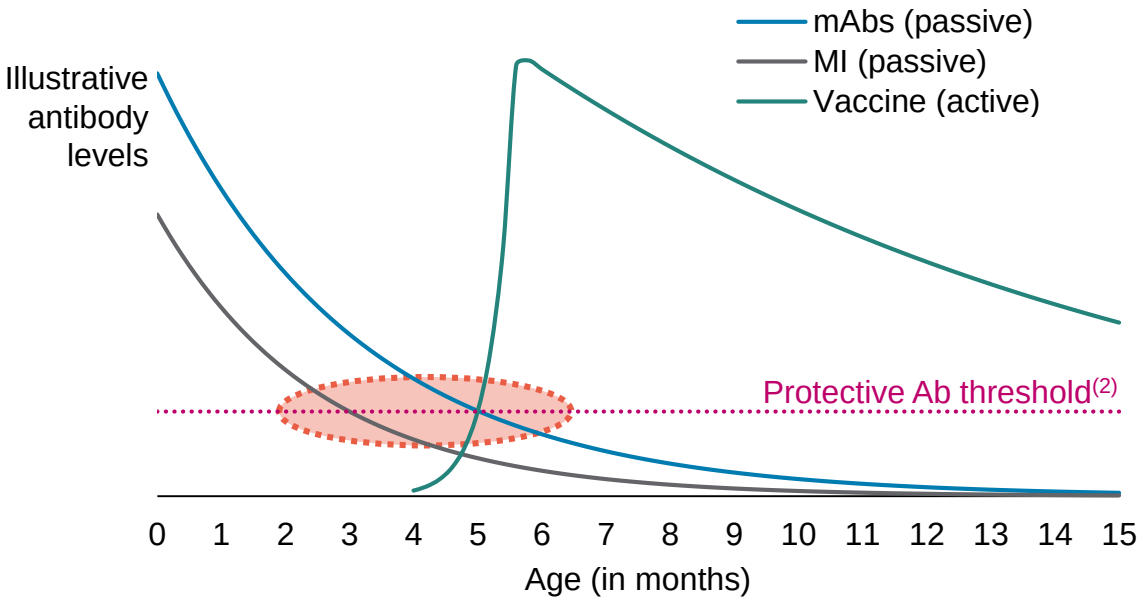
- Only known approach to provide sufficient Ab titer to all infants in 1st RSV season, when the risk of RSV hospitalization is the highest

Maternal immunization:

- Ab titers likely to drop below threshold at month 3 or earlier(1) making it impossible to cover entire cohort

Active immunization:

- Likely not feasible the first months of life



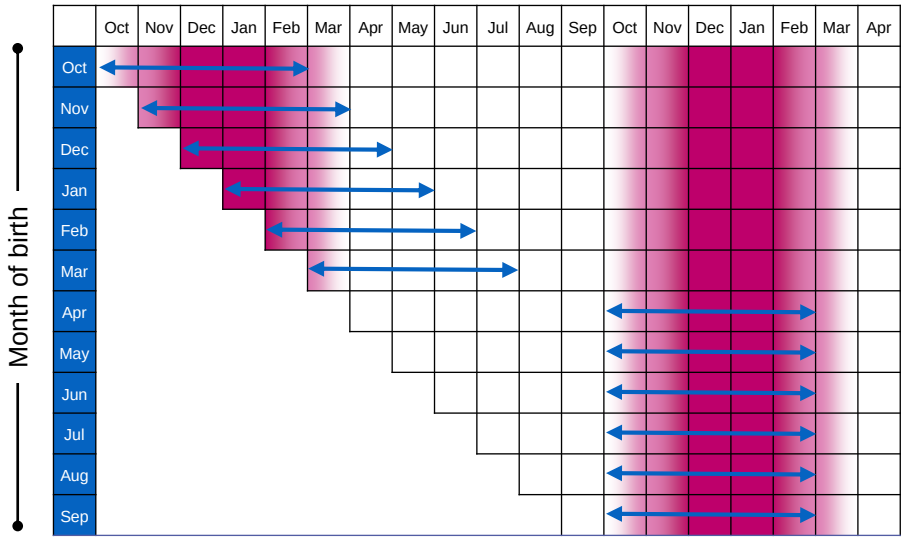
Sanofi approach: nirsevimab protecting all infants in 1st season; active immunization 2nd & 3rd seasons

Ab: Antibody; mAb; monoclonal Antibody; MI: maternal immunization
(1) (1) Depending on vaccination timing (2) Theoretical threshold
Note: Nirsevimab under investigation in collaboration with AstraZeneca, not approved by regulators

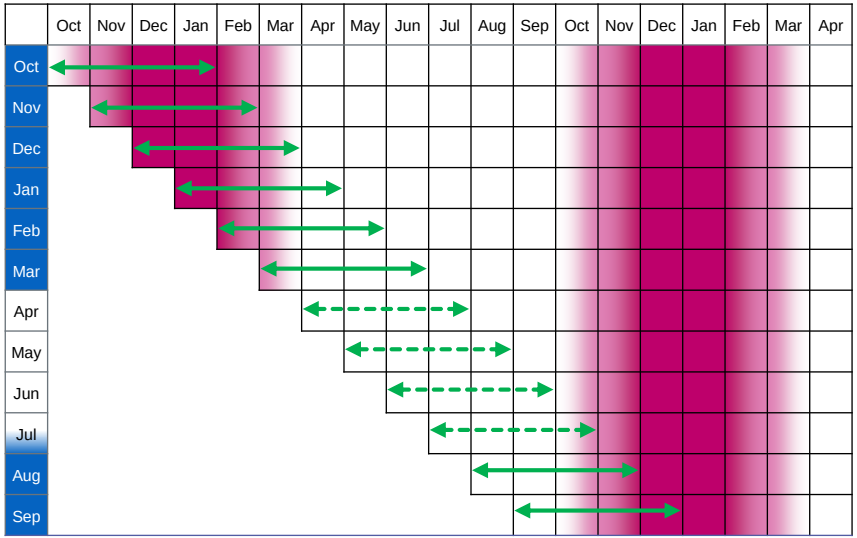
Nirsevimab prophylaxis would benefit all infants, regardless of when they are born

Modelling the period of potential protection from RSV infection in a temperate country(1)

Using mAb immunization with 5m protection



Using maternal immunization with 4m protection

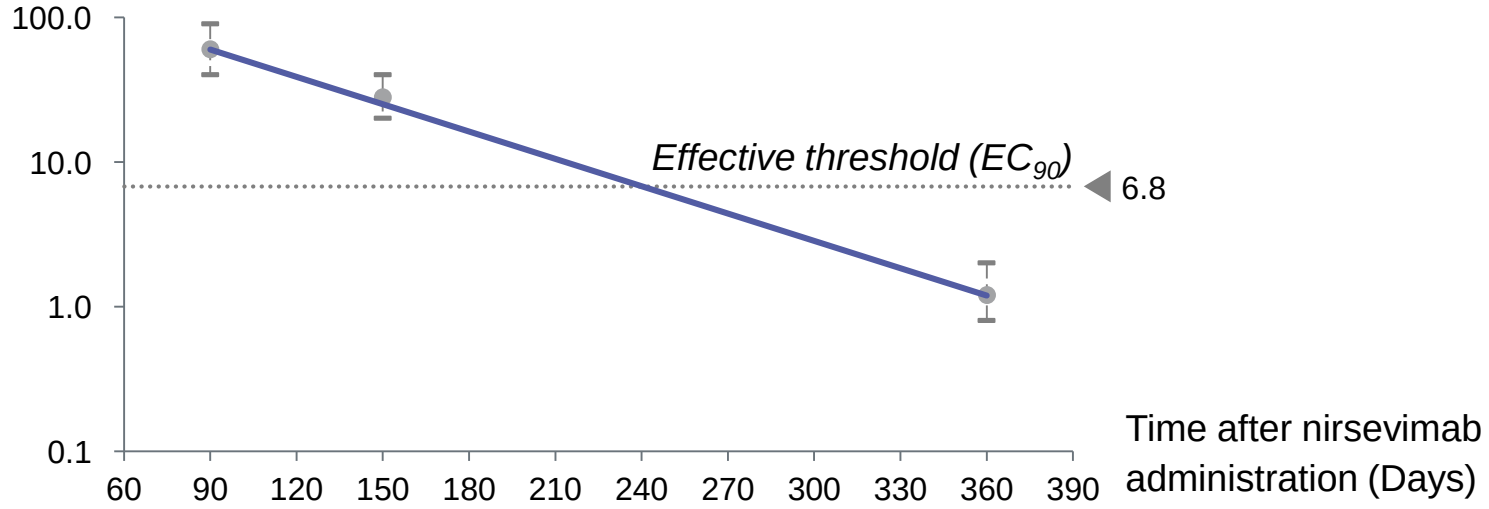


Cohorts likely benefiting from vaccine
Period of RSV disease incidence
Period of mAb protection
Period of maternal immunization
Maternal immunization ineffective

(1) Janet, Broad, Snape, Human Vaccines & Immunotherapeutic, 2017 – example of the UK, assuming RSV season 16th October-12th March

Nirsevimab protection to potentially exceed 5 months

Nirsevimab serum concentrations (µg/ml) – Mean ±SD(1)



Assessment of protection duration included in ph3 (infants to be followed 1 year for safety & LRTIs)

SD: Standard Deviation Source: nirsevimab Phase 2b results, Griffin et al n engl j med 383;5 July 30, 2020; Phase 2b results: on Day 151, 97.9% (833/851) of the nirsevimab recipients serum concentrations were above the targeted 90% effective concentration threshold of 6.8 µg/mL.26,31; mean serum concentrations of nirsevimab decayed mono-exponentially beyond 91 days without signs of nonlinearity
Note: nirsevimab under investigation in collaboration with AstraZeneca, not approved by regulators

Overview of passive immunization approaches

	Palivizumab (marketed)	**Nirsevimab** (target profile)	**Maternal immunization** (development project)
Recommended population (% of birth cohort)	**<2%** CHD/CLD & ≤29wGA	**100%** Pre- and full-term Born in- and out-season	**~40-60%**(1) Full-term only Born in-season only
Achievable immunization (% of birth cohort)	**<2%**(2) Pediatric vaccination	**~90-100%**(2) Pediatric immunization	**~20-40%**(3) Maternal vaccination
Observed efficacy (risk reduction of RSV hospitalization)	**45-55%**(4) Label (Trial 1: N=1,502; Trial 2: N=1,287)	**78%** Phase 2b (N=1,453)	
Treatment burden	**Up to 5 injections** Monthly doses in RSV season	**Single injection** Covering full first season	**Single injection** Covering only part of season

CHD: congenital heart disease; CLD: chronic lung disease
(1) Depending on the actual duration of protection (from 2 to 4 months); source: Janet, Broad, Snape, Human Vaccines & Immunotherapeutic, 2017 (2) Vaccination Coverage by Age 24 Months Among Children Born in 2015 and 2016 — National Immunization Survey-Child, United States, 2016–2018. Hill et al. MMWR 2019 (3) Influenza and Tdap Vaccination Coverage Among Pregnant Women — United States, April 2018. Khan et al. MMWR 2018 (4) Palivizumab prescribing information – range between Trial 1 and Trial 2
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NIrsevimab under investigation in collaboration with AstraZeneca, not approved by regulators

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Conclusion

John Shiver

Global Head of R&D, Sanofi Pasteur

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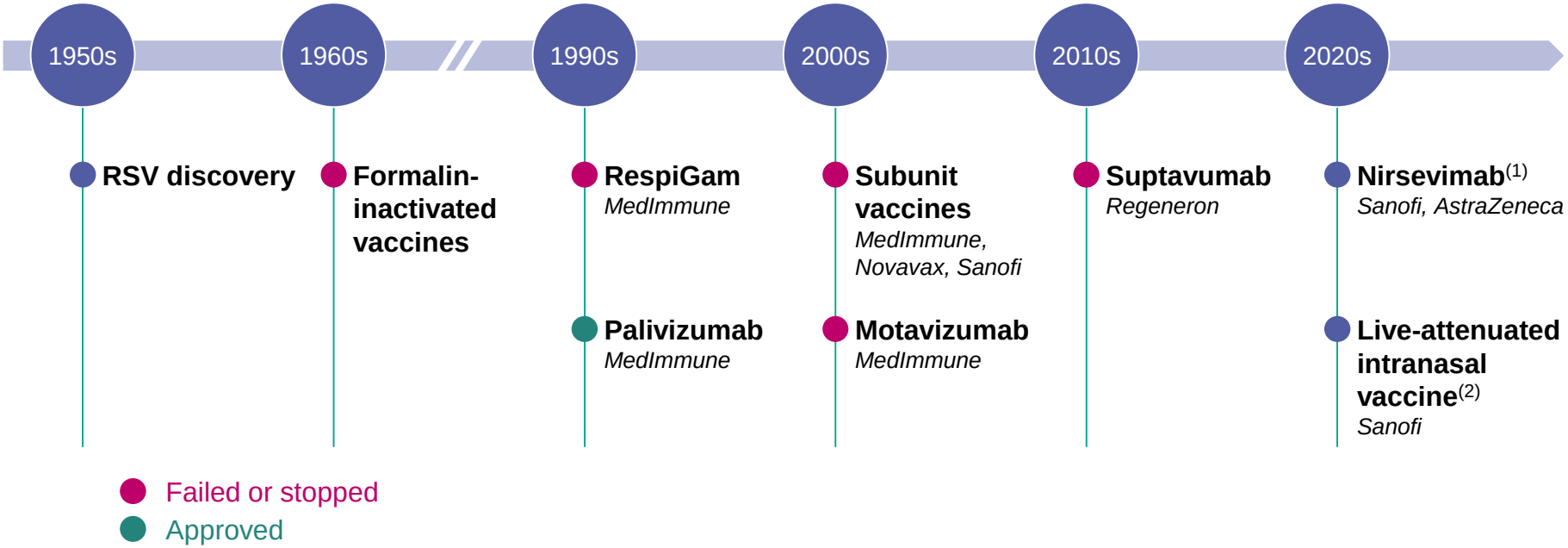
Learning from 60+ years of R&D in RSV to deliver next generation mAb and infant vaccine



mAb; monoclonal Antibody
(1) In phase 3; (2) In phase 1/2
Note: Nirsevimab under investigation in collaboration with AstraZeneca, not approved by regulators

Three pivotal studies to enable universal RSV immunization

wGA	Study	Target population	Study end
	MELODY Pivotal Ph 3 vs. placebo N=3,000 (targeted)	Healthy full-term and late pre-term infants ≥ 35 wGA	2023e
	PHASE 2b N=1,453 vs. placebo	Healthy pre-term infants 29-35 wGA	✓
	MEDLEY Ph 2/3 vs. palivizumab N=1,500 (targeted)	Palivizumab-eligible population 1st RSV season: infants ≤ 35 wGA(1) 2nd RSV season: children < 24 mo with CLD/CHD	2022e

Target submission of registration dossier: 2023e

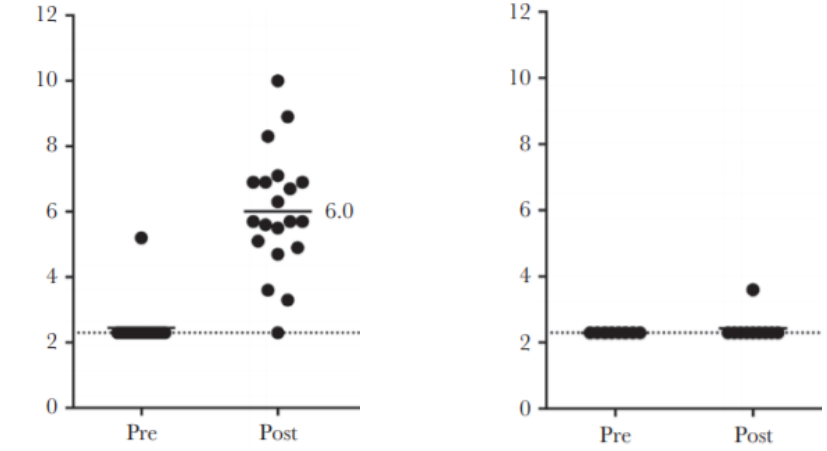
(1) Depending on local recommendation
CHD: congenital heart disease; CLD: chronic lung disease; wGA: weeks gestational age
Note: Nirsevimab under investigation in collaboration with AstraZeneca, not approved by regulators

Intranasal live-attenuated vaccine for 2nd & 3rd RSV seasons

- Leverages decades of rational attenuation of RSV by NIH
- Utilizes natural route of RSV infection (intranasal) to generate appropriate immune responses
- Demonstrated safety and immunogenicity in seropositive and seronegative infants as young as 6 months of age(1)
- Preliminary data suggests approach is likely to correlate with protection(2)

Antibody titers pre & post-immunization(1)

RSV $PRNT_{60}$ ($1/Log_2$)



RSV/ΔNS2/Δ1313/I1314L **Placebo**

Currently in phase 1/2 study conducted by NIH and JHU

NIH: National Institutes of Health; JHU: Johns Hopkins University; PRNT: Plaque reduction neutralization antibody titers

(1) Karron RA et al, J Infect Dis (2019) pii: jiz408 (2) Karron R, RSVVW, 2019

Summary - aiming for RSV prophylaxis for all infants

Recommended population	**Universal, targeting all infants** • Pre- and full-term • Born in- and out-season
Efficacy	**70-80% observed relative risk reduction** of RSV related complications in pre-term infants
Treatment burden	**One single injection** for the entire first season
Market Access	**A cost-effective** all infant strategy, **priced in line with other premium priced pediatric vaccines**

Note: Nirsevimab under investigation in collaboration with AstraZeneca, not approved by regulators

Q&A session

Thomas Triomphe
Global Head of Sanofi Pasteur

Jon Heinrichs
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Global Head of Medical, Sanofi Pasteur

John Shiver
Global Head of R&D, Sanofi Pasteur

Paul Hudson
Chief Executive Officer

John Reed
Global Head of R&D

Jean-Baptiste de Chatillon
Chief Financial Officer

Nirsevimab

Appendices

July 30, 2020

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Phase 2b demographics and baseline characteristics

	Nirsevimab N=969	Placebo N=484
Age (months)	3.29 (2.22)	3.28 (2.31)
Weight (kg) on day 1	4.60 (1.92)	4.51 (1.96)
Male	501 (51.7%)	260 (53.7%)
Race		
White	693 (71.6%)	355 (73.3%)
Black or African American	189 (19.5%)	67 (13.8%)
Asian	5 (0.5%)	10 (2.1%)
American Indian or Alaskan Native	0	1 (0.2%)
Native Hawaiian or other Pacific Islander	8 (0.8%)	3 (0.6%)
Other	61 (6.3%)	43 (8.9%)
Multiple categories checked	12 (1.2%)	5 (1.0%)
Gestational age (weeks)	32.7 (1.4)	32.7 (1.5)
Gestational age >29 to ≤ 32 weeks	326 (35.0%)	165 (35.6%)
Gestational age >32 weeks	606 (65.0%)	299 (64.4%)
Siblings enrolled in the study	336 (34.7%)	172 (35.5%)

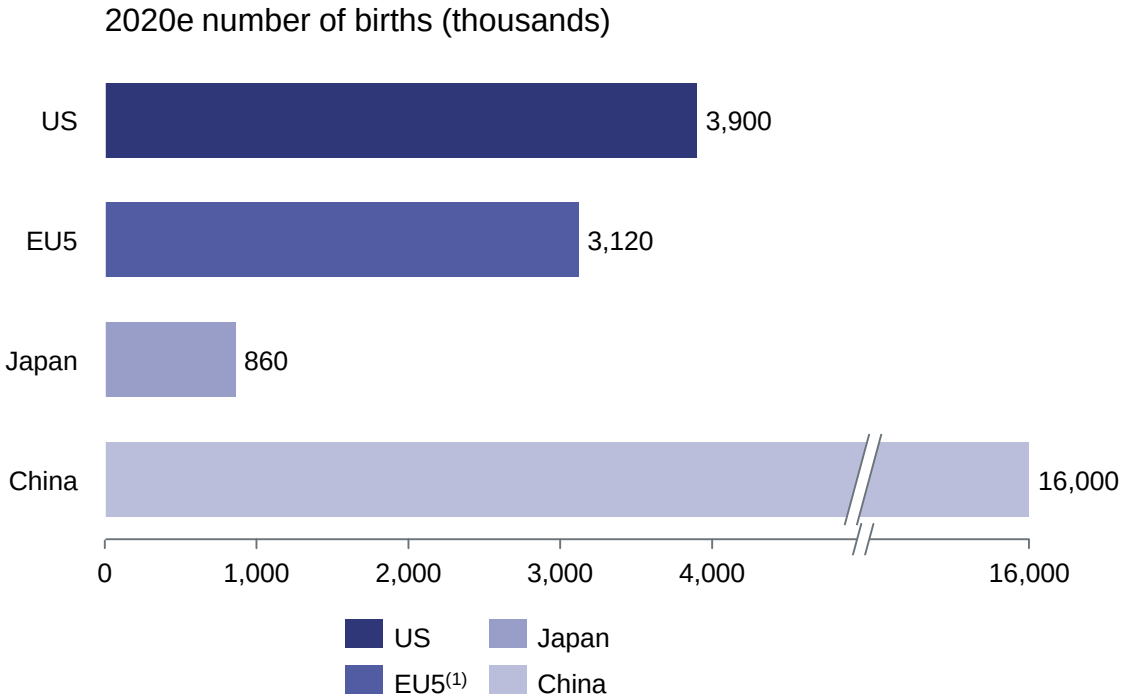
Mean (SD): age, weight, GA
N (%): male, race, GA group, siblings enrolled
Source: Nirsevimab Phase 2b results, Griffin et al n engl j med 383;5 July 30, 2020

Nirsevimab - one of the largest RSV development programs

	Player	Phase	ID	Size	Arms	Primary endpoint
Maternal immunization	GSK	Phase 2	NCT04126213	600	3: formulations 1 & 2 + PBO	Safety (AEs/SAEs) – Completed
	Pfizer	Phase 3	NCT04424316	6900	1 active group + PBO	Medically attended LRTI – Started
	Novavax	Phase 2	NCT01960686	720	8: low dose + 4 levels of Aluminum adjuvant, high dose + 3 levels of Aluminum adjuvant + PBO	Immunogenicity and safety - Achieved
		Phase 3	NCT02624947	4,636	2: active group + PBO	Medically attended LRTI - Failed
Passive immunization	Merck	Phase 1/2	NCT03524118	180	6: 4 arms pre-terms infants, with increasing doses, 1 arm full term + PBO	Safety (AEs/SAEs) - Ongoing
	Regeneron	Phase 3	NCT02325791	1,177	4: 1 dose, 2 doses, 1 dose + PBO, PBO	Medically attended LRTI – Failed
	Sanofi	Phase 2b	NCT02878330	1,453	2: active group + PBO	Medically attended LRTI - Achieved
		Phase 3	NCT03979313	3,000	2: active group + PBO	Medically attended LRTI – Started
		Phase 2/3	NCT03959488	1,500	2: active group + Palivizumab	Medically attended LRTI – Started

PBO: Placebo

Nirsevimab: RSV



Source: US Census Bureau Population Division; EU Eurostat; National Institute of Population and Social Security Research; World Bank
(1) Germany, France, Italy, Spain & United Kingdom

Summary of deal terms with AstraZeneca

- In March 2017, Sanofi and AstraZeneca announced an agreement to develop and commercialize nirsevimab jointly
- Sanofi made an upfront payment of €120m and is obligated to pay up to €495m upon achievement of development and sales-related milestones
- The two companies will share all costs and profits equally(1)
  - AstraZeneca leads all development activity through initial approvals and will retain manufacturing activities
  - Sanofi will lead commercialization activities

(1) In November 2018, AstraZeneca announced Swedish Orphan Biovitrum AB (Sobi) has the right to participate in payments that may be received from the U.S. profits or losses for nirsevimab