

## Media Update

### *Pediatric research at ReSViNET 2023 underscores Beyfortus' potential to prevent RSV disease in infants*

**Paris, February 21, 2023.** Research reinforcing Beyfortus' consistency in reducing respiratory syncytial virus (RSV) lower respiratory tract infections requiring medical care in infants, presented at the 7th Respiratory Syncytial Virus Foundation (ReSViNET) Conference in Lisbon, Portugal from February 22-24, 2023.

#### ***Jean-François Toussaint***

Global Head of Research and Development Vaccines, Sanofi

*"The winters' surges in RSV disease highlight again how this seasonal respiratory virus causes immense disruption to families and health systems every year. The new Beyfortus data are consistent with all data accumulated to date and confirm its strong profile, with an almost 80 percent reduction in medically attended RSV infections in the lungs of infants. We are on the precipice of reaching this much needed public health goal."*

### *MELODY full cohort data confirms high and consistent efficacy results*

Among the key data to be presented at ReSViNET are the safety and efficacy findings from the full cohort of the phase 3 MELODY clinical trial investigating Beyfortus in healthy late preterm and term infants (35 weeks gestational age or greater) entering their first RSV season.<sup>1</sup> These presentations strengthen Beyfortus' consistency in demonstrating an efficacy of approximately 80% against medically attended RSV lower respiratory tract infections.<sup>2</sup> The safety profile of Beyfortus was similar to placebo.<sup>1</sup>

Along with the MELODY full cohort data, 24 abstracts and presentations at ReSViNET will detail the seasonal burden of RSV and the importance of a preventative option that could help protect the broad infant population with one dose for the entire RSV season. Featured RSV presentations at ReSViNET 2023:

- Safety and Efficacy of Nirsevimab for Prevention of Medically Attended RSV Lower Respiratory Tract Infection in All Infants Enrolled in the Phase 3 Melody Trial. Oral presentation number 35; Session III (11:40am-1pm); EPIC SANA Lisboa Hotel, Morus Hall.
- Evaluating the Disease Burden of RSV Infections in Young Children in Primary Care: a Systematic Literature Review. Poster presentation number 115; EPIC SANA Lisboa Hotel, Foyer.
- Seasonality of Infant Lower Respiratory Tract Infections, Including those Caused by RSV, Was Altered During the COVID-19 Pandemic: Results from Four US Health Systems. Poster presentation number 84; EPIC SANA Lisboa Hotel, Foyer.
- Infant hospitalizations and ICU Admissions for Bronchiolitis and RSV-BRONCHIOLITIS Are at Historic Highs During 2022 Early Seasonal Disease: Results From Four US Health Systems. Poster presentation number 85; EPIC SANA Lisboa Hotel, Foyer.

Beyfortus, being developed by Sanofi and AstraZeneca, is the only RSV protective option for the broad infant population, including those born healthy, at term or preterm, or with specific health conditions. Beyfortus' single administration can be timed to correspond with the beginning of the RSV season for babies born prior to the season and at birth for those born during the RSV season (November to March).<sup>3</sup> In clinical trials, Beyfortus demonstrated protection for at least five months.<sup>4</sup>

RSV is the most common cause of lower respiratory infections, including bronchiolitis and pneumonia in infants.<sup>5</sup> It is also a leading cause of hospitalization in all infants.<sup>5-9</sup> Globally, in 2019, there were approximately 33 million cases of acute lower respiratory infections leading to more than three million hospitalizations, and it was estimated that there were 26,300 in-hospital deaths of children younger than five years.<sup>10</sup> RSV-related direct medical costs, globally – including hospital, outpatient and follow-up care – were estimated at €4.82 billion in 2017.<sup>11</sup>

## About Beyfortus

Beyfortus®, a long-acting antibody designed for all infants for protection against RSV disease from birth through their first RSV season with a single dose, is developed jointly by Sanofi and AstraZeneca.

Beyfortus has been developed to offer newborns and infants direct RSV protection via an antibody to help prevent medically attended lower respiratory tract infections caused by RSV. Monoclonal antibodies do not require the activation of the immune system to help offer timely, rapid and direct protection against the disease.<sup>12</sup>

Beyfortus has been granted marketing authorization in the European Union and the United Kingdom for the prevention of RSV lower respiratory tract disease in newborns and infants from birth during their first RSV season.<sup>4</sup>

In March 2017, Sanofi and AstraZeneca announced an [agreement](#) to develop and commercialize Beyfortus. Under the terms of the agreement, AstraZeneca leads all development and manufacturing activities and Sanofi will lead commercialization activities and record revenues. Under the terms of the global agreement, Sanofi made an upfront payment of €120m, has paid development and regulatory milestones of €55m and will pay up to a further €440m upon achievement of certain regulatory and sales-related milestones. The two companies share all costs and profits.

Beyfortus has been granted designations to facilitate expedited development by several regulatory agencies around the world. These include Breakthrough Therapy Designation by The China Center for Drug Evaluation under the National Medical Products Administration; [Breakthrough Therapy Designation](#) from the US Food and Drug Administration; access granted to the European Medicines Agency (EMA) [PRIority MEdicines \(PRIME\) scheme](#); Promising Innovative Medicine designation by the UK Medicines and Healthcare products Regulatory Agency; and has been named “a medicine for prioritized development” under the Project for Drug Selection to Promote New Drug Development in Pediatrics by the Japan Agency for Medical Research and Development (AMED). The safety and efficacy of Beyfortus was evaluated under an accelerated assessment procedure by the EMA.

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### About Sanofi

We are an innovative global healthcare company, driven by one purpose: we chase the miracles of science to improve people’s lives. Our team, across some 100 countries, is dedicated to transforming the practice of medicine by working to turn the impossible into the possible. We provide potentially life-changing treatment options and life-saving vaccine protection to millions of people globally, while putting sustainability and social responsibility at the center of our ambitions.

Sanofi is listed on Euronext: SAN and NASDAQ: SNY

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#### Sanofi Forward-Looking Statements

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